

2/24/00 12:58 pm

Notification Tracking Sheet

=====

Bp number: 00-054-09n

=====

App number: 2000-174XRAB
 Received: 2/23/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 3/24/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C)
 Begin movement: 2/22/00
 End movement: 2/21/01
 Begin release: 2/22/00
 End release: 2/21/01
 Acre: 20.00
 CBI status: CBI
 Fax: 636-737-7085

- | | Initial | Date |
|--|-----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [2/24/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>ZST</i>]* | [2/28/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KZO</i>] | [2/29/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	KS	*	*SCR *
Interstate	*Dest*	MT	*	*WR *
Interstate	*Orig*	KS	*	*SCR *
Interstate	*Orig*	MT	*	*WR *
Release	*	*MT	*	4*WR *

[]	[]
[]	[]
[]	[]

- | | | |
|---|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [2/28/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> denial/withdraw | [<i>KZO</i>] | [3/5/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KZO</i>] | [3/22/00] |

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-174XRAB

Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-054-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-174XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite

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Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-174XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --
(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

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Monsanto Reference ID

2000-174XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] Bozeman, MT, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

MT

*[(b) (4), (b) (6), (b) (7)(C)] Cascade County/Province, MT, [(b) (4), (b) (6), (b) (7)(C)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MT, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, [(b) (4), (b) (6), (b) (7)(C)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] Bozeman, MT, [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

*[(b) (4) Gallatin County/Province, MT, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) Bozeman, MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[Pat (b) (4), (b) (6), (b) (7)(C) Judith Basin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) SA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS
*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2000-174XRAB

MT

*[(b) (4), (b) (6), (b) (7)(C)] Cascade County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2000-174XRAB

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (4)

MT

(b) (4), (b) (6), (b) (7)(C) Cascade County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Gallitin County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Gallitin County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Judith Basin County/Province, MT, USA, 5 acres.

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005743

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

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Monsanto Reference ID

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Permit Unit

February 22, 2000

USDA, APHIS, PPQ, BSS

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Riverdale, MD 27037

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1. USDA Reference Number

2. Applicant Reference Number 2000-174XRAB

3. Applicant/Responsible Party

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63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:
KS, MT

DESTINATION:
KS, MT

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MT

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

[CBI Deleted] -- *Gallatin County/Province, MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

MT

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (4)

MT

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres

[CBI Deleted] -- Gallitin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Gallitin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Judith Basin County/Province, MT, USA, 5 acres

CBI-DELETED

Monsanto Reference ID
2000-174XRAB

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CBI-DELETED

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005756

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1. USDA Reference Number

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St. Louis

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Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 --

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

*[(b) (4)] Sedgwick County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b) (4), (b) (6), (b) (7)(C)] Cascade County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

*[(b) (4) Gallatin County/Province, MT, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Judith Basin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

KS

*[M (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

MT

*[(b) (4), (b) (6), (b) (7)(C)] Cascade County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4)] Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

*[(b) (4), (b) (6), (b) (7)(C)], Judith Basin County/Province, MT, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (4)

MT

[(b) (4), (b) (6), (b) (7)(C)] Cascade County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4), (b) (6), (b) (7)(C)] Gallatin County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4)

Gallatin County/Province, MT, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C)

Judith Basin County/Province, MT, USA, 5 acres.

CONFIDENTIAL

Monsanto Reference ID

2000-174XRAB

RESPONSIBLE PERSON/RESEARCHER:
(b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE: (314) 694-1000

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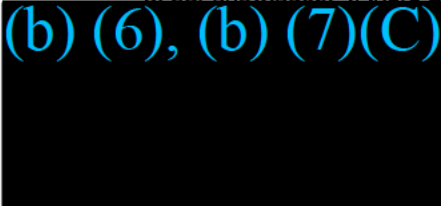
Monsanto Reference ID

2000-174XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 22, 2000

OR120018_BR_005766

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-174XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 22, 2000

00-054-09n

1. USDA Reference Number

2. Applicant Reference Number 2000-174XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 22, 2000 - March 23, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/ Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* ~~CTP2~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* ~~CTP2~~ gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 1500 pounds of wheat seed to and from each location.

ORIGIN:

KS, MT

DESTINATION:

KS, MT

Ship From:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

MT

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

[CBI Deleted] -- *Gallatin County/Province, MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

Ship To:

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID
2000-174XRAB

MT

[CBI Deleted] -- *Cascade County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID
2000-174XRAB

[CBI Deleted] -- *Judith Basin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-174XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (4)

MT

[CBI Deleted] -- Cascade County/Province, MT, USA, 5 acres

[CBI Deleted] -- Gallitin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Gallitin County/Province, MT, USA, 5 acres

[CBI Deleted] -- Judith Basin County/Province, MT, USA, 5 acres

CBI-DELETED

Monsanto Reference ID
2000-174XRAB

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-174XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 22, 2000

OR120018_BR_005779

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-054-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-09n	Applicant #:	2000-174XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005780

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 24, 2000

Dear Dr. Gingery:

Enclosed is notification 00-054-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-09n	Applicant #:	2000-174XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005781



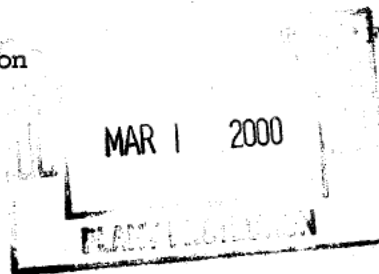
United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 24, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-054-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-09n	Applicant #:	2000-174XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

*state acknowledges receipt of
this notification but cannot
evaluate*

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: Kansas

Rptloc01/R4

MAR 15 2000



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OR120018_BR_005782



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

February 24, 2000

Dear Dr. Gingery:

Enclosed is notification 00-054-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-054-09n	Applicant #:	2000-174XRAB
Received:	February 23, 2000	Effective:	March 24, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

✓

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Lori M. Witham

Signature:

(b) (6), (b) (7)(C)

Date:

3/2/00

State:

Montana

Rptloc01/R4



March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-09n (2000-174XRAB)
Regulated article - Wheat
Destinations - Kansas, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

T. Sim, Kansas State Board of Agric., Topeka, KS
G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-054-09n

OR120018_BR_005784

Confirmation Report-Memory Send

Time : Mar-21-00 04:06pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 233
Date : Mar-21 04:05pm
To : 916367377085
Document Pages : 01
Start time : Mar-21 04:05pm
End time : Mar-21 04:06pm
Pages sent : 01
Job number : 233

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 20, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 24, 2000.

Interstate movement and Release
Notification no. 00-054-09a (2000-174XRAB)
Regulated article - Wheat
Destinations - Kansas, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
T. Sam, Kansas State Board of Agric., Topeka, KS
G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

July 25, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

The following wheat sites for release have been canceled.

USDA # 00-040-09n, Monsanto # 2000-97XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Heppner Morrow County, OR

(b) (4)

Lincoln County, OR

USDA # 00-059-03n, Monsanto # 2000-182XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4)

Thompson County, (b) (6), (b) (7)(C), (b) (4) ND

(b) (6), (b) (7)(C), (b) (4) Trail County ND

USDA # 00-054-06n, Monsanto # 2000-170XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Cass County ND

USDA # 00-054-09n, Monsanto # 2000-174XRAB

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Galletin County, MT

USDA # 00-059-07n, Monsanto # 2000-188XRAB

(b) (4)

(b) (4) Minndoka County, ID

(b) (4)

(b) (4) Canyon County ID

If you need further information, please contact me at (b) (6), (b) (7)(C)

OR120018_BR_005786

apb
7/27/00

MONSANTO

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Sincerely,

(b) (6), (b) (7)(C)

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

cc J. Griesbach, Oregon Dept. of Agriculture, Salem, OR
D. Nelson, North Dakota Dept. of Agriculture, Bismarck, ND
E. Gingerly, Montana Dept. of Agriculture, Helena, MT
F. Vega, Idaho Dept. of Agriculture, Boise, ID
R. Stoaks, USDA, APHIS, Sacramento, CA

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KD - File

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

July 19, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's wheat notification USDA # 00-054-09n,
Monsanto # 2000-174XRAB, it was discovered a release county
was incorrectly entered. The notification should have read

(b) (6), (b) (7)(C), (b) (4) Fergus County, MT.

I apologize for any inconvenience that this may cause. Please call
me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc: G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005788

MONSANTO



July 31, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notification USDA # 00-054-09n, Monsanto # 2000-174XRAB. It was discovered an incorrect county was given. (b) (6), (b) (7)(C), (b) (4) is located in Fergus County, not (b) (6), (b) (7)(C), (b) (4) as previously stated.

If you have any questions, please call at (b) (6), (b) (7)(C)

Sincerely,
(b) (6), (b) (7)(C)

cc: R. Stoaks, USDA, APHIS, PPQ, Sacramento, CA
M. Bryson Agri Science Division, Helena, MT.

2000 Wheat Field Trial Report
USDA # 00-054-09n Monsanto # 2000-174XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
Site 1	Cascade	MT	(NOT PLANTED)
Site 2	Gallatin	MT	(NOT PLANTED)
Site 3	Gallatin	MT	
Site 4	Fergus	MT	

Gallatin County, MT- Site 3

Planting Date: April 16, 2000

Destruct Date: July 8, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Gallatin County, MT – Site 3

Planting Date: April 16, 2000

Destruct Date: July 27, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Fergus County, MT- Site 4

Planting Date: May 19, 2000

Harvest Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, Line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Additional Comments: [CBI deleted]

2000 Wheat Field Trial Report
USDA # 00-054-09n Monsanto # 2000-174XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Cascade	MT (NOT PLANTED)
Site 2	Gallatin	MT (NOT PLANTED)
Site 3	Gallatin	MT
Site 4	Fergus	MT

Gallatin County, MT- Site 3

Planting Date: April 16, 2000

Destruct Date: July 8, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of Trial: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting

(b) (4)

(b) (4)

Gallatin County, MT – Site 3

Planting Date: April 16, 2000

Destruct Date: July 27, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, 33512

Purpose of Trial:

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Fergus County, MT- Site 4

Planting Date: May 19, 2000

Harvest Date: August 24, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, Line 33512

Purpose of Trial: (b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

Additional Comments: (b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 29, 2000.

Interstate movement and Release
Notification no. 00-059-01n (2000-179XRAB)
Regulated article - Wheat
Destinations - Iowa, Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

Permit Unit

February 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number

2. Applicant Reference Number 2000-179XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: IR

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-179XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1300 pounds of wheat seed to and from each location

ORIGIN:

IA, KS, ND

DESTINATION:

IA, KS, ND

Ship From:

IA

* (b) (4) Cass County/Province, IA, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

* (b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-179XRAB

*[(b) (4), (b) (6), (b) (7)(C)] Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

IA

*[(b) (4)] Cass County/Province, IA, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

*[(b) (4)] Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

*[(b) (4), (b) (6), (b) (7)(C)] Cass County/Province, ND

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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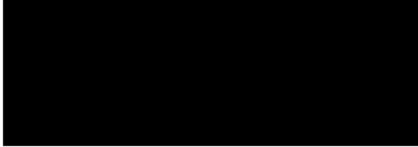
MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-179XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
February 24, 2000

OR120018_BR_005804

MONSANTO



May 22, 2002

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
<http://www.monsanto.com>

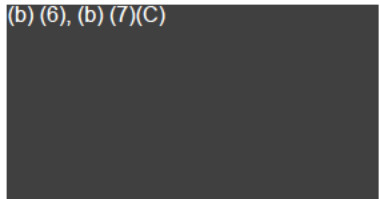
Mary Jackson
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale MD

Dear Ms. Jackson;

Please find the final reports for the following USDA notifications enclosed.

Monsanto #	USDA #
2000-78XRAB	00-038-19n
2000-89XRAB	00-039-10n
2000-566XRAB	00-231-07n
2000-102XRAB	00-040-11n
2000-179XRAB	00-059-01n

(b) (6), (b) (7)(C)



OR120018_BR_005805

2000 Wheat Field Trial Report
USDA # 00-059-01n Monsanto # 2000-179XRAB

Biotech Field Compliance Team
July 11, 2001
Monsanto Company

Location	County	State
Site 1	Cass	ND
Site 2	Cass	ND

Cass County, ND Site 1

(b) (4)

Cass County, ND –Site 1

(b) (4)

(b) (4)

Cass County, ND --Site 2

(b) (4)

Cass County, ND Site 2

(b) (4)

3/06/00 7:20 am

Notification Tracking Sheet

=====
Bp number: 00-059-01n
=====

App number: 2000-179XRAB
Received: 2/28/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/29/00
Phenotype: IR - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 2/24/00
End movement: 2/23/01
Begin release: 2/24/00
End release: 2/23/01
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|---------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ayd] | [3/6/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | []* | [3/6/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLn] | [3/7/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*IA	*	*SCR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Dest*ND	*	*SCR *
Interstate	*Orig*IA	*	*SCR *
Interstate	*Orig*KS	*	*SCR *
Interstate	*Orig*ND	*	*SCR *
Release	* *ND	*	2*SCR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ayd] | [3/7/2000] |
| 6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw | [KLn] | [3/29/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLn] | [4/3/00] |

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

Permit Unit

February 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-059-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-179XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: IR

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [(b)(4)
(b)(4)

CBI

Gene: CTP7-CP4 -- [(b)(4)
(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [(b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [(b)(4)
(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1300 pounds of wheat seed to and from each location

ORIGIN:

IA, KS, ND

DESTINATION:

IA, KS, ND

Ship From:

IA

*[(b)(4) Cass County/Province, IA (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

ND

*[(b)(4), (b)(6), (b)(7)(C) Cass County/Province, ND

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

*[Lowell Jahnke Farm, 1052 3rd St N, Casselton, Cass County/Province, ND, 58012, USA

CONTACT: Stephen Valenti, Monsanto Company, 4517 Quail Run Avenue, Sioux Falls, SD,
57105, U.S.A., 605/334-3350

] - CBI

Ship To:

IA

*[(b)(4) Cass County/Province, IA, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

KS

*[(b)(4) Sedgwick County/Province, KS, (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

ND

*[(b)(4), (b)(6), (b)(7)(C) Cass County/Province, ND

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-179XRAB

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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Monsanto Reference ID
2000-179XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 24, 2000

OR120018_BR_005816

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 24, 2000

00-059-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-179XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: IR

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 1300 pounds of wheat seed to and from each location

ORIGIN:

IA, KS, ND

DESTINATION:

IA, KS, ND

Ship From:

IA

[CBI Deleted] -- *Cass County/Province, IA, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

Ship To:

IA

[CBI Deleted] -- *Cass County/Province, IA, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND

CBI-DELETED

Monsanto Reference ID
2000-179XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2000-179XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005828

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-179XRAB

February 24, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

00-059-01n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-179XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Cheserfield Parkway North
St. Louis MO 63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category:

Phenotype:

Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 1300 pounds of wheat seed to and from each location

ORIGIN:

IA, KS, ND

DESTINATION:

IA, KS, ND

Ship From:

IA

[CBI Deleted] -- *Cass County/Province, IA, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

Ship To:

IA

[CBI Deleted] -- *Cass County/Province, IA, U.S.A.

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

ND

[CBI Deleted] -- *Cass County/Province, ND

CBI-DELETED

Monsanto Reference ID
2000-179XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-179XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-179XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005836

file copy

Mr. Charles Stoltenow
IA Department of Agriculture and Land Stewardship
First Floor, Wallace building
East 9th Street and Grand Avenue
Des Moines, IA 50319

March 6, 2000

Dear Mr. Stoltenow:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005837

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

March 6, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005838

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005839



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Charles Stoltenow
IA Department of Agriculture and Land Stewardship
First Floor, Wallace building
East 9th Street and Grand Avenue
Des Moines, IA 50319

March 6, 2000

Dear Mr. Stoltenow:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

D. DeWeese, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: C. R. Stoltenow

Signature: (b) (6), (b) (7)(C)

Date: March 16, 2000

State: Iowa

Rptloc01/R4



MAR 16 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

March 6, 2000



Dear Mr. Sim IV:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

~~State concurs with APHIS determination.~~

~~State DOES NOT CONCUR and offers the following reasons:~~

Name of State official: Thomas Sim IV

Signature: (b) (6), (b) (7)(C)

Date: 3/6/00

State: Kansas

Rptloc01/R4

*State acknowledges receipt of
PPQ notification, but cannot
evaluate this
information.*





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-059-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-01n	Applicant #:	2000-179XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IA KS ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David A Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



APHIS - Protecting American Agriculture

OR120018_BR_005842

An Equal Opportunity Employer

NO. 460 P. 4

ND AG DEPT

MAR. 9. 2000 4:19PM

March 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 29, 2000.

Interstate movement and Release
Notification no. 00-059-01n (2000-179XRAB)
Regulated article - Wheat
Destinations - Iowa, Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

C. Stoltenow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-059-01n

OR120018_BR_005843

Confirmation Report-Memory Send

Time : Mar-30-00 07:13pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 561
Date : Mar-30 07:12pm
To : 916367377085
Document Pages : 01
Start time : Mar-30 07:12pm
End time : Mar-30 07:13pm
Pages sent : 01
Job number : 561

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 29, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63128

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 29, 2000.

Interstate movement and Release
Notification no. 00-059-01n (2000-179XRAB)
Regulated article - Wheat
Destinations - Iowa, Kansas, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

C. Stoltencow, Iowa Dept. of Agric. and Land Stewardship, Des Moines, IA
T. Sim, Kansas State Board of Agric., Topeka, KS
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPO, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005844

3/06/00 7:20 am

Notification Tracking Sheet

=====
Bp number: 00-059-02n
=====

App number: 2000-181XRAB
Received: 2/28/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/29/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)**
Begin movement: 2/24/00
End movement: 2/23/01
Begin release: 2/24/00
End release: 2/23/01
Acre: 10.00
CBI status: CBI
Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ayd]	[3/6/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[K&L]*	[3/6/00]*
3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fedex</i>	[K&L]	[3/7/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	ND	*	*SCR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	ND	*	*SCR *
Release	*	*ND	*	2*SCR *

5. <input checked="" type="checkbox"/> Enter genes into database	[ayd]	[3/7/2000]
6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw	[K&L]	[4/17/00]*
7. <input checked="" type="checkbox"/> Enter final data into database	[K&L]	[4/18/00]

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-181XRAB

Permit Unit

February 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-059-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-181XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [REDACTED]

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 -- [REDACTED]

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [REDACTED]

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [REDACTED]

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520, TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 3' -- (b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [REDACTED] (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- (b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:
MO, ND

DESTINATION:
MO, ND

Ship From:

MO

*[(b) (4) St. Louis County/Province, MO (b) (4)
U.S.A.]

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

ND

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-181XRAB

Ship To:

MO

*[(b) (4)] U.S.A., St. Louis County/Province, MO, (b) (4)

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] MO,
[(b) (4), (b) (6), (b) (7)(C)] U.S.A., [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

ND

*[(b) (4), (b) (6), (b) (7)(C)] Cass County/Province, ND

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] SD,
[(b) (4), (b) (6), (b) (7)(C)] U.S.A., [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

*[(b) (4), (b) (6), (b) (7)(C)] Cass County/Province, ND, [(b) (4), (b) (6), (b) (7)(C)] USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C)] SD,
[(b) (4), (b) (6), (b) (7)(C)] U.S.A., [(b) (4), (b) (6), (b) (7)(C)]

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-181XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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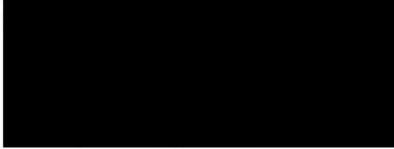
Monsanto Reference ID

2000-181XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

February 24, 2000

OR120018_BR_005857

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-181XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

February 24, 2000

00-059-02n

1. USDA Reference Number

2. Applicant Reference Number 2000-181XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Cheserfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID
2000-181XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:

MO, ND

DESTINATION:

MO, ND

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2000-181XRAB

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID
2000-181XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

MONSANTO

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-181XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005874

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MONSANTO COMPANY
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ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-181XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

February 24, 2000

00-059-02n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-181XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company
700 Cheserfield Parkway North
St. Louis MO 63198

4. Duration of Introduction

Interstate Movement and Release

February 24, 2000 - March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: 33512, 35710, 35845

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S537, TA S317, TA S621, TA S635, TA S1081, TA S2520. TA S5070, TA S5450

Constructs: PV-TXGT13

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S2747, TA S8691

Constructs: PV-TXGT15

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: M1 3' -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S7327, TA S9240

Constructs: PV-TXGT17

GENE OF INTEREST

Promoter: CMP3/15-1 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S 7886

Constructs: PV-TXGT22

GENE OF INTEREST

Promoter: CMP3/15-3 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

designation of transformed line: TA S7535, TA S9215

Constructs: PV-TXGT23

GENE OF INTEREST

Promoter: CMP3/15-2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 2000 pounds of wheat seed to and from each location.

ORIGIN:

MO, ND

DESTINATION:

MO, ND

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A

ND

[CBI Deleted] -- *Cass County/Province, ND

[CBI Deleted] -- *Cass County/Province, ND, USA

CBI-DELETED

Monsanto Reference ID

2000-181XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND (2)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

[CBI Deleted] -- Cass County/Province, ND, USA, 5 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

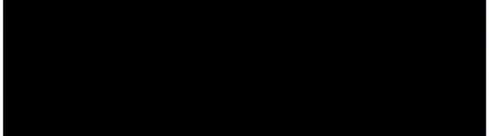
Monsanto Reference ID
2000-181XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
February 24, 2000

OR120018_BR_005886

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 6, 2000

Dear Mr. Brown:

Enclosed is notification 00-059-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-02n	Applicant #:	2000-181XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005887

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-059-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-02n	Applicant #:	2000-181XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005888



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 6, 2000

Dear Mr. Brown:

Enclosed is notification 00-059-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-02n	Applicant #:	2000-181XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rptloc01/R4

MAR 14 2000



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OR120018_BR_005889

An Equal Opportunity Employer

P.09/12 314751005

DEPT OF AGRICULTURE

MAR-14-2000 14:15



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-059-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	00-059-02n	Applicant #:	2000-181XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

A. Dianne Mathew, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

DAVID R NELSON

Signature:

(b) (6), (b) (7)(C)

Date:

3-9-2000

State:

ND

Rptloc01/R4

APR 11 2000



APHIS - Protecting American Agriculture

OR120018_BR_005890

AN EQUAL OPPORTUNITY EMPLOYER

2 P. 322 NO.

ND AG DEPT

APR 11 2000 1:20PM

April 17, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 17, 2000.

Interstate movement and Release
Notification no. 00-059-02n (2000-181XRAB)
Regulated article - Wheat
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-059-02n

OR120018_BR_005891

Confirmation Report-Memory Send

Time : Apr-17-00 03:38pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 999
Date : Apr-17 03:36pm
To : 916367377085
Document Pages : 01
Start time : Apr-17 03:37pm
End time : Apr-17 03:37pm
Pages sent : 01
Job number : 999

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 17, 2000

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 17, 2000.

Interstate movement and Release
Notification no. 00-059-02n (2000-181XRAB)
Regulated article - Wheat
Destinations - Missouri, North Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers. (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO



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OR120018_BR_005892

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

In reviewing Monsanto's acknowledged wheat notifications, it was discovered there was an omitted line number. The following are the affected notifications.

USDA #	Monsanto #
00-041-03n	2000-108XRAB
00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005893

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T. Wessels, Washington Dept. of Agric., Jefferson City, MO

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

OR120018_BR_005894

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

August 10, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

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00-041-06n	2000-111XRAB
00-041-04n	2000-109XRAB
00-059-02n	2000-181XRAB

I apologize for any inconvenience this may cause, please call me at (b) (6), (b) (7)(C) if you have any questions.

Sincerely,

(b) (6), (b) (7)(C)

cc M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
D. DeWeese, PPQ, SCR, Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric, Pierre, SD
G. Gingery, Montana Dept. of Agric, Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA

OR120018_BR_005895

MONSANTO

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T. Wessels, Washington Dept. of Agric., Jefferson City, MO

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

OR120018_BR_005896

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-059-02n Monsanto #2000-181XRAB

October 31, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303606	Cass	ND
2147303607	Cass	ND

Cass County/ND (2147303606)

(b)(4)

(b)(4)

Cass County/ND (2147303607)

(b)(4)

(b)(4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-059-02n Monsanto #2000-181XRAB

October 31, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147303606	Cass	ND
2147303607	Cass	ND

Cass County/ND (2147303606)

Planting Date: 05/08/2000

Harvest Date: 08/14/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Planting Date: 05/09/2000

Harvest Date: 08/18/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Cass County/ND (2147303607)

Planting Date: 05/09/2000

Harvest Date: 08/14/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

3/06/00 7:20 am

Notification Tracking Sheet

=====
Bp number: 00-059-07n
=====

App number: 2000-188XRAB
Received: 2/28/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/29/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: 636-737-6032
Begin movement: 3/25/00
End movement: 3/24/01
Begin release: 3/25/00
End release: 3/24/01
Acre: 20.00
CBI status: CBI
Fax: 636-737-7085
=====

- | | Initial | Date |
|--|----------|--------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [3/6/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [KSH]* | [3/6/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KSH] | [3/7/00]* |
| 4. [] State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*ID	*	*WR *
Interstate	*Dest*KS	*	*SCR *
Interstate	*Orig*ID	*	*WR *
Interstate	*Orig*KS	*	*SCR *
Release	* *ID	*	4*WR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [3/6/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KSH] | [3/27/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KSH] | [3/28/00] |

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-188XRAB

February 24, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-059-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-188XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 25, 2000

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-188XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [REDACTED] (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [REDACTED] (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 3600 pounds of wheat seed to and from each location.

ORIGIN:
ID, KS

DESTINATION:
ID, KS

Ship From:

ID

*[(b) (4) Cassia County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C), ID, 83301,
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C), ID, (b) (4), (b) (6), (b) (7)(C),
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Bingham
County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C), ID, (b) (4), (b) (6), (b) (7)(C),
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

* (b) (4) Canyon County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

* (b) (4) Minndoka County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

KS

* (b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

ID

* (b) (4) Cassia County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

*[(b) (4) Twin Falls County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

(b) (4) Bingham
County/Province, ID, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Canyon County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

*[(b) (4) Minndoka County/Province, ID, USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C)
USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-188XRAB

KS

*[(b) (4) Sedgwick County/Province, KS, (b) (4) USA

CONTACT:
USA

(b) (4), (b) (6), (b) (7)(C)

ID

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4)

ID

[(b) (4)] Cassia County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4)] Bingham
County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4)] Minndoka County/Province, ID, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

] - CBI

[(b) (4)] Canyon County/Province, ID, USA, 5 acres.

CONFIDENTIAL

Monsanto Reference ID
2000-188XRAB

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ID, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-188XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005914

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

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Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-188XRAB

Permit Unit

February 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-059-07n

1. USDA Reference Number

2. Applicant Reference Number 2000-188XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 25, 2000

MARCH 24, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 3600 pounds of wheat seed to and from each location.

ORIGIN:

ID, KS

DESTINATION:

ID, KS

Ship From:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

[CBI Deleted] -- *Canyon County/Province, ID, USA

[CBI Deleted] -- *Minndoka County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Bingham County/Province, ID, USA

[CBI Deleted] -- *Canyon County/Province, ID, USA

[CBI Deleted] -- *Minndoka County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4)

ID

[CBI Deleted] -- Cassia County/Province, ID, USA, 5 acres

[CBI Deleted] -- Bingham County/Province, ID, USA, 5 acres

[CBI Deleted] -- Minndoka County/Province, ID, USA, 5 acres

[CBI Deleted] -- Canyon County/Province, ID, USA, 5 acres

CBI-DELETED

Monsanto Reference ID

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MONSANTO

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CBI-DELETED

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2000-188XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005930

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-188XRAB

Permit Unit

February 24, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-059-071

1. USDA Reference Number

2. Applicant Reference Number 2000-188XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 25, 2000

MARCH 24, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Interstate Movement and Release

Ship up to 3600 pounds of wheat seed to and from each location.

ORIGIN:

ID, KS

DESTINATION:

ID, KS

Ship From:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Bingham County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

[CBI Deleted] -- *Canyon County/Province, ID, USA

[CBI Deleted] -- *Minndoka County/Province, ID, USA

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

Ship To:

ID

[CBI Deleted] -- *Cassia County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

[CBI Deleted] -- *Twin Falls County/Province, ID, USA

[CBI Deleted] -- *Bingham County/Province, ID, USA

[CBI Deleted] -- *Canyon County/Province, ID, USA

[CBI Deleted] -- *Minndoka County/Province, ID, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

KS

[CBI Deleted] -- *Sedgwick County/Province, KS, USA

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ID (4)

ID

[CBI Deleted] -- Cassia County/Province, ID, USA, 5 acres

[CBI Deleted] -- Bingham County/Province, ID, USA, 5 acres

[CBI Deleted] -- Minndoka County/Province, ID, USA, 5 acres

[CBI Deleted] -- Canyon County/Province, ID, USA, 5 acres

CBI-DELETED

Monsanto Reference ID

2000-188XRAB

MONSANTO

Food · Health · Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-188XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2000

OR120018_BR_005940

file copy

Dr. Rogelio R. Vega
Division of Plant Industries
Idaho Department of Agriculture
2270 Old Penitentiary Road
Boise, ID 83712

March 6, 2000

Dear Dr. Vega:

Enclosed is notification 00-059-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-07n	Applicant #:	2000-188XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005941

file copy

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

March 6, 2000

Dear Mr. Sim IV:

Enclosed is notification 00-059-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-059-07n	Applicant #:	2000-188XRAB
Received:	February 28, 2000	Effective:	March 29, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	ID KS		
Release destination:	ID		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005942

March 27, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 29, 2000.

Interstate movement and Release
Notification no. 00-059-07n (2000-188XRAB)
Regulated article - Wheat
Destinations - Idaho, Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
R. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-059-07n

OR120018_BR_005943

Confirmation Report-Memory Send

Time : Mar-27-00 06:05pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 457
Date : Mar-27 06:01pm
To : 916367377085
Document Pages : 01
Start time : Mar-27 06:02pm
End time : Mar-27 06:05pm
Pages sent : 01
Job number : 457

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 27, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 29, 2000.

Interstate movement and Release
Notification no. 00-059-07n (2000-188XRAB)
regulated article - wheat
Destinations - Idaho, Kansas

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

CC:
A. Vega, Idaho Dept. of Agric., Boise, ID
T. Sim, Kansas State Board of Agric., Topeka, KS
R. Steaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO



APHIS - Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_005944

2000 Wheat Field Trial Report
USDA # 00-059-07n Monsanto # 2000-188XRAB

(b) (6), (b) (7)(C)

June 8, 2000
Monsanto Company

Location	County	State	
Monsanto Company	Cassia	ID	
Monsanto Company	Bingham	ID	
Monsanto Company	Minndoka	ID	(NOT PLANTED)
Monsanto Company	Canyon	ID	(NOT PLANTED)

Cassia County, ID

(b)(4)

Bingham County, ID

(b)(4)

(b)(4)

(b)(4)

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63108

PHONE (314) 694-1000

<http://www.monsanto.com>

July 25, 2000

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker;

The following wheat sites for release have been canceled.

USDA # 00-040-09n, Monsanto # 2000-97XRAB

(b) (4), (b) (6), (b) (7)(C)

Heppner Morrow County, OR

(b) (4)

Lincoln County, OR

USDA # 00-059-03n, Monsanto # 2000-182XRAB

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Thompson County, (b) (4), (b) (6), (b) (7)(C) ND

(b) (4), (b) (6), (b) (7)(C) Trail County ND

USDA # 00-054-06n, Monsanto # 2000-170XRAB

(b) (4)

(b) (4) Cass County ND

USDA # 00-054-09n, Monsanto # 2000-174XRAB

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Galletin County, MT

USDA # 00-059-07n, Monsanto # 2000-188XRAB

Monsanto Company

Rupert, Minndoka County, ID

Monsanto Company

Nampa, Canyon County ID

If you need further information, please contact me at (b) (6), (b) (7)(C)

OR120018_BR_005947

apl
7/27/00

MONSANTO

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Sincerely

(b) (6), (b) (7)(C)

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

cc J. Griesbach, Oregon Dept. of Agriculture, Salem, OR
D. Nelson, North Dakota Dept. of Agriculture, Bismarck, ND
E. Gingerly, Montana Dept. of Agriculture, Helena, MT
F. Vega, Idaho Dept. of Agriculture, Boise, ID
R. Stoaks, USDA, APHIS, Sacramento, CA

OR120018_BR_005948

2000 Wheat Field Trial Report

USDA # 00-059-07n

Monsanto # 2000-188XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
Site 1	Cassia	ID	
Site 2	Bingham	ID	
Site 3	Minndoka	ID	(NOT PLANTED)
Site 4	Canyon	ID	(NOT PLANTED)

Cassia County, ID – Site 1

(b) (4)

Bingham County, ID – Site 2

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

2000 Wheat Field Trial Report
USDA # 00-059-07n Monsanto # 2000-188XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
Site 1	Cassia	ID	
Site 2	Bingham	ID	
Site 3	Minndoka	ID	(NOT PLANTED)
Site 4	Canyon	ID	(NOT PLANTED)

Cassia County, ID – Site 1

Planting Date: April 7, 2000

Destruct/Harvest Date: July 27, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness, and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

General Results of Field Trial: [CBI deleted]

Bingham County, ID – Site 2

Planting Date: April 11, 2000

Destruct Date: July 28, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT12 line 33512

Purpose of trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

General Results of Field Trial: [CBI deleted]

CBI-DELETED

3/06/00 7:20 am

Notification Tracking Sheet

Bp number: 00-062-03n

App number: 2000-164XRAB
 Received: 3/02/00
 Institution: Monsanto
 Recipient: Wheat
 Status: Pending
 Effective date: 4/01/00
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person:
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C)

Begin movement: 3/31/00
 End movement: 3/31/01
 Begin release: 3/31/00
 End release: 3/31/01
 Acre: 20.00
 CBI status: CBI

Fax: 636-737-7085

	Initial	Date
1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry	[ajd]	[3/6/2000]
2. <input checked="" type="checkbox"/> Review by biotechnologist	[SMK]*	[3/6/2000]*
3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex	[KZL]	[3/7/00]*
4. <input type="checkbox"/> State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MN	*	*NER	*	[]
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Dest*	ND	*	*SCR	*	[]
Interstate	*Dest*	WA	*	*WR	*	[]
Interstate	*Orig*	MN	*	*NER	*	
Interstate	*Orig*	MO	*	*SCR	*	
Interstate	*Orig*	ND	*	*SCR	*	
Interstate	*Orig*	WA	*	*WR	*	
Release	*	MN	*	1*NER	*	[]
Release	*	ND	*	1*SCR	*	[]
Release	*	WA	*	1*WR	*	[]

5. <input checked="" type="checkbox"/> Enter genes into database	[ajd]	[3/6/2000]
6. <input checked="" type="checkbox"/> Letter of acknowledgement/denial/withdraw	[KZL]	[4/4/00]*
7. <input type="checkbox"/> Enter final data into database	[KZL]	[4/5/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-164XRAB

Permit Unit

March 01, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-062-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-164XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 31, 2000 - March 31, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant Glyphosate tolerant

Cultivar/Variety Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33463, 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b)(4)

CBI

Gene: CTP7-CP4 -- (b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-164XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 15,000 pounds of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, WA

DESTINATION:

MN, MO, ND, WA

Ship From:

MN

*[(b)(4) Wilkin County/Province,
MN, (b)(4)

CONTACT:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C)
MN, (b)(4), (b)(6), (b)(7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C)
MO, (b)(4), (b)(6), (b)(7)(C)
U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

*[(b)(4) St. Louis, St. Louis County/Province, MO (b)(4)

CONTACT:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C)
MO (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID
2000-164XRAB

ND

*[(b)(4)] McHenry County/Province, ND (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) ND (b)(4), (b)(6), (b)(7)(C) USA,

] - CBI

WA

*[(b)(4)] Grant County/Province, WA (b)(4) USA

CONTACT: (b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

Ship To:

MN

*[(b)(4)] Wilkin County/Province,
MN, (b)(4)

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) MN, (b)(4), (b)(6), (b)(7)(C)

] - CBI

MO

*[(b)(4)] St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
MO (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-164XRAB

*[(b)(4)] St. Louis County/Province, MO, (b)(4)

CONTACT: [(b)(4), (b)(6), (b)(7)(C)] MO [(b)(4), (b)(6), (b)(7)(C)]

] - CBI

ND

*[(b)(4)] McHenry County/Province, ND, (b)(4) USA

CONTACT: [(b)(4), (b)(6), (b)(7)(C)] ND, [(b)(4), (b)(6), (b)(7)(C)] USA,

] - CBI

WA

*[(b)(4)] Grant County/Province, WA, (b)(4) USA

CONTACT: [(b)(4), (b)(6), (b)(7)(C)] WA, [(b)(4), (b)(6), (b)(7)(C)]
USA, [(b)(4), (b)(6), (b)(7)(C)]

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-164XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), ND (1), WA (1)

MN

(b)(4) Wilkin County/Province,
MN, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) MN, (b)(4), (b)(6), (b)(7)(C)

] - CBI

ND

(b)(4) McHenry County/Province, ND, USA, 5 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) ND, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

WA

(b)(4) Grant County/Province, WA, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) WA, (b)(4), (b)(6), (b)(7)(C) USA, (b)(4), (b)(6), (b)(7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-164XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 01, 2000

OR120018_BR_005963

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

St. Louis, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-164XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 01, 2000

00-062-03n

1. USDA Reference Number

2. Applicant Reference Number 2000-164XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

March 31, 2000 - March 31, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33463, 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Interstate Movement and Release

Ship up to 15,000 pounds of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, WA

DESTINATION:

MN, MO, ND, WA

Ship From:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

[CBI Deleted] -- *St. Louis County/Province, MO

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), ND (1), WA (1)

MN

[CBI Deleted] -- Wilkin County/Province, MN, 5 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 5 acres

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 10 acres

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-164XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 01, 2000

OR120018_BR_005974

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MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-164XRAB

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

March 01, 2000

00-062-03n

1. **USDA Reference Number**
2. **Applicant Reference Number** 2000-164XRAB
3. **Applicant/Responsible Party**

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North
St. Louis MO 63198

Phone
FAX
EMail

(b) (6), (b) (7)(C)

636/737-7085

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

March 31, 2000 - March 31, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant Glyphosate tolerant

Cultivar/Variety Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33463, 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 15,000 pounds of wheat seed to and from each location.

ORIGIN:

MN, MO, ND, WA

DESTINATION:

MN, MO, ND, WA

Ship From:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

Ship To:

MN

[CBI Deleted] -- *Wilkin County/Province, MN

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

[CBI Deleted] -- *St. Louis County/Province, MO

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

WA

[CBI Deleted] -- *Grant County/Province, WA, USA

CBI-DELETED

Monsanto Reference ID

2000-164XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN (1), ND (1), WA (1)

MN

[CBI Deleted] -- Wilkin County/Province, MN, 5 acres

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 5 acres

WA

[CBI Deleted] -- Grant County/Province, WA, USA, 10 acres

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MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

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PHONE (314) 694-1000

<http://www.monsanto.com>

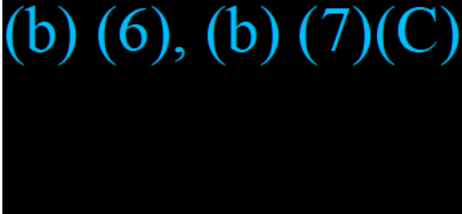
Monsanto Reference ID

2000-164XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 01, 2000

OR120018_BR_005982

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 6, 2000

Dear Dr. Hanks:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005983

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 6, 2000

Dear Mr. Brown:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005984

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005985

file copy

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 6, 2000

Dear Mr. Wessels:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_005986



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 6, 2000

Dear Dr. Hanks:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 4-4-00

State: MN

Rptloc01/R4

APR 4 2000





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 6, 2000

Dear Mr. Brown:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

 ✓ State concurs with APHIS determination.

 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rptloc01/R4

MAR 14 2000



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OR120018_BR_005988

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P.04/12 3147510005

DEPT OF AGRICULTURE

MAR-14-2000 14:19



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 6, 2000

Dear Mr. Nelson:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	00-062-03n	Applicant #:	2000-164XRAB
Received:	March 2, 2000	Effective:	April 1, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND WA		
Release destination:	MN ND WA		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Katmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-9-2000

State: ND

Rptloc01/R4

MAR 10 2000



APHIS - Protection of Agriculture
P. 3 NO. 460

OR120018_BR_005989

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ND AG DEPT

MAR. 9. 2000 4:18PM



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 6, 2000

Dear Mr. Wessels:

Enclosed is notification 00-062-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-062-03n Applicant #: 2000-164XRAB
Received: March 2, 2000 Effective: April 1, 2000
Institution: Monsanto Recipient: Wheat
Interstate destination: MN MO ND WA
Release destination: MN ND WA

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

R. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Thomas L. Wessels

Signature: (b) (6), (b) (7)(C)

Date: 3/8/00

State: WA

Rptloc01/R4



MAR 8 2000

April 4, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 4, 2000.

Interstate movement and Release
Notification no. 00-062-03n (2000-164XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, North Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
T. Wessels, Washington Dept. of Agric., Olympia, WA

OR120018_BR_005991

S. Wood, PPQ, NER, Raleigh, NC
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-062-03n

Confirmation Report-Memory Send

Time : Apr-17-00 03:40pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 001
Date : Apr-17 03:37pm
To : 916367377085
Document Pages : 01
Start time : Apr-17 03:39pm
End time : Apr-17 03:40pm
Pages sent : 01
Job number : 001

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

April 4, 2000

(b) (6), (b) (7)(C)

Consent Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear Ms. Hunter:

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 4, 2000.

Interstate movement and release
Notification no. 00-062-03n (2000-164XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, North Dakota, Washington

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers. (Biotechnology).

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
T. Wessels, Washington Dept. of Agric., Olympia, WA
S. Wood, PPQ, NER, Raleigh, NC
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA



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OR120018_BR_005993

2000 Wheat Field Trial Report
USDA # 00-062-03n Monsanto # 2000-164XRAB

Biotech Field Compliance Team
July 26, 2001
Monsanto Company

Location

Site 1

Site 2

Site 3

County

Grant

McHenry

Wilkin

State

WA

ND

MN

Site 1

(b)(4)

Site 1

(b)(4)

(b)(4)

Site 2

(b)(4)

Site 2

(b)(4)

(b)(4)

Site 3

(b)(4)

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-062-03n Monsanto # 2000-164XRAB

Biotech Field Compliance Team
July 26, 2001
Monsanto Company

Location	County	State
Site 1	Grant	WA
Site 2	McHenry	ND
Site 3	Wilkin	MN

Site 1

Planting Date: April 20, 2000

Destruct Date: August 16-17, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]
plants.] - CBI

Field Monitoring for Plant Growth, Weediness and Plant Growth Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Site 1

Planting Date: April 20, 2000

Harvest Date: August 16-17, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391; PV-TXGT12, line 33512

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

Site 2

Planting Date: April 21, 2000

Harvest Date: August 10, 2000

CBI-DELETED

Destruct Date: August 11, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512, line 33463.

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Devitalization or Final Disposition of Plot area after Harvest: [CBI deleted]

Site 2

Planting Date: April 28, 2000

Harvest Date: August 10, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, lines 33391,33463; PV-TXGT12, line 33512.

Purpose of trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Additional Comments: [CBI deleted]

Site 3

Planting Date: May 4, 2000

Harvest Date: August 25, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [All harvested seed was shipped to Monsanto -St. Louis.] - CBI

Additional Comments: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-062-03n Monsanto #2000-164XRAB

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7958	Wilkin	MN
7408	McHenry	ND
519	Grant	WA

Wilkin County/MN (7958)

Planting Date: 04/28/2000

Harvest Date: 08/10/2000

Vector Constructs/Line Numbers Planted:
(b) (4) - CBI

(b) (4)

Purpose of Field Trial:
(b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand:

(b) (4)

(b) (4)

Disposition of the Harvested Material:

- CBI

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Additional Comments:

(b) (4)

(b) (4)

McHenry County/ND (7408)

Planting Date: 05/04/2000

Harvest Date: 08/25/2000

Vector Constructs/Line Numbers Planted:

(b) (4)

(b) (4)

Purpose of Field Trial:

(b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand:

(b) (4)

(b) (4)

Disposition of the Harvested Material:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Additional Comments:

(b) (4)

(b) (4)

Grant County/WA (519)

Planting Date: 04/20/2000

Harvest Date: 08/16/2000

Vector Constructs/Line Numbers Planted:

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand:

(b) (4)

(b) (4)

Disposition of the Harvested Material:
(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:
(b) (4)

(b) (4)

Monitoring for Volunteer Plants:
(b) (4)

(b) (4)

Additional Comments:

(b) (4)

Planting Date: 04/21/2000

Harvest Date: 08/10/2000

Vector Constructs/Line Numbers Planted:
(b) (4)

(b) (4)

Purpose of Field Trial:

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand:

(b) (4)

(b) (4)

Disposition of the Harvested Material:

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:
(b) (4)

(b) (4)

Monitoring for Volunteer Plants:

(b) (4)

(b) (4)

Additional Comments:

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-062-03n Monsanto #2000-164XRAB

AMENDED
December 17, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
7958	Wilkin	MN
7408	McHenry	ND
519	Grant	WA

Wilkin County/MN (7958)

Planting Date: 04/28/2000

Harvest Date: 08/10/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

McHenry County/ND (7408)

Planting Date: 05/04/2000

Harvest Date: 08/25/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Grant County/WA (519)

Planting Date: 04/20/2000

Harvest Date: 08/16/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Planting Date: 04/21/2000

Harvest Date: 08/10/2000

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

3/08/00 8:08 am

Notification Tracking Sheet

=====
Bp number: 00-067-08n
=====

App number: 2000-238XRAB
Received: 3/07/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/06/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 4/05/00
End movement: 4/05/01
Begin release: 4/05/00
End release: 4/05/01
Acre: 1.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|----------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [ajd] | [3/8/2000] |
| 2. <input type="checkbox"/> Review by biotechnologist | [AMK]* | [3/9/2000]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State Fed-ex | [KLN] | [3/9/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Release	* *MT	*	*WR *

- | | | |
|--|---------|--------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [ajd] | [3/9/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [KLN] | [3/27/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [KLN] | [3/28/00] |

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PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-238XRAB

Permit Unit

March 06, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-067-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-238XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 05, 2000 - April 05, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, McNeal MT9433, MT9653, or MTHW9701

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP2/15 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID
2000-238XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 40 pounds of wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From:

MO

* [REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT:

(b)(6), (b)(4), (b)(7)(C) MO,
(b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

MT

* [REDACTED] (b)(4) Gallatin County/Province, MT, (b)(4)

CONTACT:

(b)(6), (b)(4), (b)(7)(C) MT, (b)(6), (b)(4), (b)(7)(C)
(b)(6), (b)(4), (b)(7)(C)

] - CBI

Ship To:

MO

* [REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

CONTACT: (b) (6), (b) (4), (b) (7)(C) MO,
(b) (6), (b) (4), (b) (7)(C) U.S.A., (b) (6), (b) (4), (b) (7)(C)

] - CBI

MT

*[(b)(4) Gallatin County/Province, MT, (b)(4)

CONTACT: (b) (6), (b) (4), (b) (7)(C) MT (b) (6), (b) (4), (b) (7)(C)
(b) (6), (b) (4), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[(b)(4) Gallitin County/Province, MT, USA, 1 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (6), (b) (4), (b) (7)(C) MT (b) (6), (b) (4), (b) (7)(C)

] - CBI

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-238XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 06, 2000

OR120018_BR_006017

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY

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ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-238XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 06, 2000

00-067-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-238XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 05, 2000 - April 05, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, McNeal MT9433, MT9653, or MTHW9701

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 40 pounds of wheat seed to and from each location.

ORIGIN:
MO, MT

DESTINATION:
MO, MT

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2000-238XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID
2000-238XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallitin County/Province, MT, USA, 1 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PARKWAY NORTH

ST. LOUIS, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

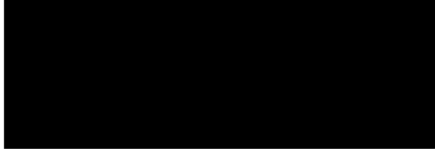
Monsanto Reference ID

2000-238XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

March 06, 2000

OR120018_BR_006029

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700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-238XRAB

March 06, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-067-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-238XRAB

3. Applicant/Responsible Party

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Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

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FAX

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(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

April 05, 2000 - April 05, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, McNeal MT9433, MT9653, or MTHW9701

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I/2 - (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I/5 -- (b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 40 pounds of wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From:

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A.,

] - CBI

MT

*[(b)(4)] Gallatin County/Province, MT, (b)(4)

CONTACT:

(b)(4), (b)(6), (b)(7)(C) MT, (b)(4), (b)(6), (b)(7)(C)

] - CBI

Ship To:

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A.

CONFIDENTIAL

Monsanto Reference ID
2000-238XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[(b)(4) Gallatin County/Province, MT, (b)(4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-238XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

(b)(4)

Gallitin County/Province, MT, USA, 1 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C) MT, (b)(4), (b)(6), (b)(7)(C)

] - CBI

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Monsanto Reference ID

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9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 06, 2000

OR120018_BR_006036

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description (referred to as vector components) category includes the names and information about genes and their expressed traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically,

Monsanto ID: 2000-238XRAB

information concerning marketing strategies, and the names of independent contractors participating in a

company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPont.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto.

Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-238XRAB

Permit Unit

March 06, 2000

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-067-08n

1. USDA Reference Number

2. Applicant Reference Number 2000-238XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

April 05, 2000 - April 05, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Bobwhite, McNeal MT9433, MT9653, or MTHW9701

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal ~~6-enolpyruvylshikimate 3-phosphate synthase~~ gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal ~~6-enolpyruvylshikimate 3-phosphate synthase~~ gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate 3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-238XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 40 pounds of wheat seed to and from each location.

ORIGIN:

MO, MT

DESTINATION:

MO, MT

Ship From:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID
2000-238XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID
2000-238XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT (1)

MT

[CBI Deleted] -- Gallitin County/Province, MT, USA, 1 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

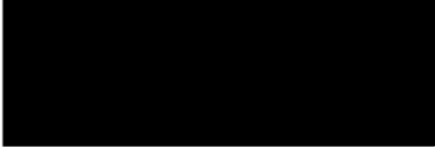
Monsanto Reference ID
2000-238XRAB

MONSANTO COMPANY
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company
March 06, 2000

OR120018_BR_006048

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-067-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-067-08n	Applicant #:	2000-238XRAB
Received:	March 7, 2000	Effective:	April 6, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006049

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

March 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-067-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-067-08n	Applicant #:	2000-238XRAB
Received:	March 7, 2000	Effective:	April 6, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO MT		
Release destination:	MT		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006050



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 8, 2000

Dear Mr. Brown:

Enclosed is notification 00-067-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-067-08n
Received: March 7, 2000
Institution: Monsanto
Interstate destination: MO MT
Release destination: MT

Applicant #: 2000-238XRAB
Effective: April 6, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 3-14-00

State: MO

Rptloc01/R4

MAR 14 2000



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OR120018_BR_006051



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

March 8, 2000

Dear Dr. Gingery:

Enclosed is notification 00-067-08n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-067-08n

Received: March 7, 2000

Institution: Monsanto

Interstate destination: MO MT

Release destination: MT

Applicant #: 2000-238XRAB

Effective: April 6, 2000

Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPO, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 3/10/00

State: Montana

Rptloc01/R4

MAR 13 2000



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OR120018_BR_006052

March 27, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 6, 2000.

Interstate movement and Release
Notification no. 00-067-08n (2000-238XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
File number 00-067-08n

OR120018_BR_006053

Confirmation Report-Memory Send

Time : Mar-27-00 05:52pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 446
Date : Mar-27 05:51pm
To : 916367377085
Document Pages : 01
Start time : Mar-27 05:52pm
End time : Mar-27 05:52pm
Pages sent : 01
Job number : 446

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

March 27, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 6, 2000.

Interstate movement and Release
Notification no. 00-067-08n (2000-238XRAB)
Regulated article - Wheat
Destinations - Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

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A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Scientific Services
Plant Protection and Quarantine

Enclosure

cc:

M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
D. DeWeese, PPQ, SCR, Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA



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OR120018_BR_006054

2000 Wheat Field Trial Report
USDA # 00-067-08n Monsanto # 2000-238XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location
Site 1

County
Gallatin

State
MT

Gallatin County, MT

Planting Date: May 4, 2000

Harvest Date: August 18, 2000 through August 22, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial:

(b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics:

(b) (4)

(b) (4)

Disposition of the Harvested Material

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-067-08n Monsanto # 2000-238XRAB

December 7, 2001

Biotech Field Compliance Team
Monsanto Company

Location	County	State
Site 1	Gallatin	MT

Gallatin County, MT

Planting Date: May 4, 2000

Harvest Date: August 18, 2000 through August 22, 2000

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI deleted]

Field Monitoring Observations for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below.¹

¹ In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

FIELD MONITORING DATA AS CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, observations concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

7/17/00 11:10 am

Notification Tracking Sheet

=====

Bp number: 00-195-04n

=====

App number: 2000-518XRAB Begin movement: 8/11/00
 Received: 7/13/00 End movement: 8/11/01
 Institution: Monsanto Begin release: 8/11/00
 Recipient: Wheat End release: 8/11/01
 Status: Pending Acre: 14.00
 Effective date: 8/12/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

- | | Initial | Date |
|--|----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>aid</i>] | [7/17/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>jt</i>]* | [7/17/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLN</i>] | [7/20/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate	*Dest*	AZ	*	*WR	*	[]
Interstate	*Dest*	HI	*	*WR	*	[]
Interstate	*Dest*	MO	*	*SCR	*	[]
Interstate	*Dest*	MT	*	*WR	*	[]
Interstate	*Orig*	AZ	*	*WR	*	
Interstate	*Orig*	HI	*	*WR	*	
Interstate	*Orig*	MO	*	*SCR	*	
Interstate	*Orig*	MT	*	*WR	*	
Release	*	AZ	*	1*WR	*	[]
Release	*	HI	*	1*WR	*	[]

- | | | |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>aid</i>] | [7/17/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLN</i>] | [8/31/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLN</i>] | [9/1/00] |

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-518XRAB

July 12, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-195-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-518XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EEmail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BZ991-408HW, BZ992-588, Express, Impervo, Brooks, West Bred 926, West Bred 936, elite lines and Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

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Monsanto Reference ID

2000-518XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 8,000 kg. wheat seeds, seedlings and leaf tissue to and from each location.

ORIGIN:
AZ, HI, MO, MT

DESTINATION:
AZ, HI, MO, MT

Ship From:

AZ

*[(b) (4) Yuma County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C)

] - CBI

HI

*[(b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-518XRAB

MT

*[(b) (4)] Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

Ship To:

AZ

*[(b) (4)] Yuma County/Province, AZ, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

HI

*[(b) (4)] Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C), MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-518XRAB

MT

*(b) (4) Gallatin County/Province, MT (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
USA (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-518XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), HI (1)

AZ

[(b) (4) Yuma County/Province, AZ, USA, 10 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) AZ, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

HI

[(b) (4) Honolulu
County/Province, HI, U.S.A., 4 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

] - CBI

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<http://www.monsanto.com>

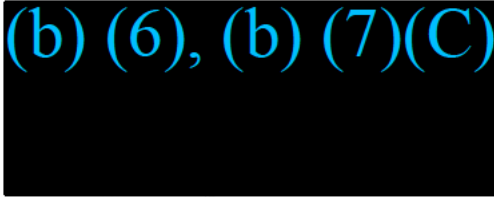
Monsanto Reference ID

2000-518XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 12, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

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Monsanto Reference ID

2000-518XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 12, 2000

00-195-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-518XRAB

3. Applicant/Responsible Party

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Phone

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636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BZ991-408HW, BZ992-588, Express, Impervo, Brooks,
West Bred 926, West Bred 936, elite lines and Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 8,000 kg. wheat seeds, seedlings and leaf tissue to and from each location.

ORIGIN:

AZ, HI, MO, MT

DESTINATION:

AZ, HI, MO, MT

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), HI (1)

AZ

[CBI Deleted] -- Yuma County/Province, AZ, USA, 10 acres

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 4 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-518XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 12, 2000

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

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Monsanto Reference ID

2000-518XRAB

July 12, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-195-04n

1. USDA Reference Number

2. Applicant Reference Number 2000-518XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

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CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

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Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 8,000 kg. wheat seeds, seedlings and leaf tissue to and from each location.

ORIGIN:

AZ, HI, MO, MT

DESTINATION:

AZ, HI, MO, MT

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-518XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

AZ (1), HI (1)

AZ

[CBI Deleted] -- Yuma County/Province, AZ, USA, 10 acres

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 4 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

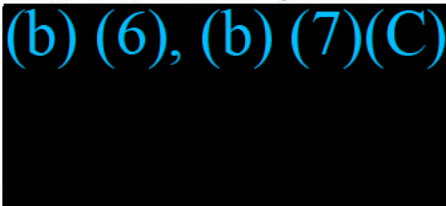
Monsanto Reference ID

2000-518XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 12, 2000

file copy

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

July 17, 2000

Dear Dr. Sobey:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006087

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006088

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006089

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

July 17, 2000

Dear Dr. Gingery:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006090



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Scott Sobey, ~~Associate Director~~
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

July 17, 2000

Dear Dr. Sobey:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-195-04n Applicant #: 2000-518XRAB
Received: July 13, 2000 Effective: August 12, 2000
Institution: Monsanto Recipient: Wheat
Interstate destination: AZ HI MO MT
Release destination: AZ HI

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 7/28/00

State: Arizona

Rptloc01/R4



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JUL 31 2000

OR120018_BR_006091

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-195-04n Applicant #: 2000-518XRAB
Received: July 13, 2000 Effective: August 12, 2000
Institution: Monsanto Recipient: Wheat
Interstate destination: AZ HI MO MT
Release destination: AZ HI

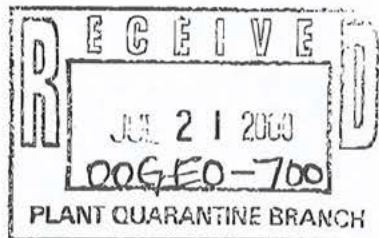
Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianné Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine



Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 30 August 2000

State: Hawaii

Post-It™ brand fax transmittal memo 7671		# of pages ▶
To <i>M. Jackson</i>	From <i>C. Okada</i>	
Co.	Co.	
Dept.	Phone #	
Fax #	Fax #	



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OR120018_BR_006092

AUG 31 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPO, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

7-24-00

State:

MO

Rptloc01/R4

JUL 25 2000



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United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

July 17, 2000

Dear Dr. Gingery:

Enclosed is notification 00-195-04n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-04n	Applicant #:	2000-518XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO MT		
Release destination:	AZ HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 7/21/00

State: Montana

Rptloc01/R4



August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear **(b) (6), (b) (7)(C)**

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-04n (2000-518XRAB)
Regulated article - Wheat
Destinations - Arizona, Hawaii, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.

OR120018_BR_006095

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

S. Soby, Arizona Dept. of Arizona, Phoenix, AZ
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-195-04n

Confirmation Report-Memory Send

Time : Aug-31-00 03:23pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 203
Date : Aug-31 03:21pm
To : 916367377085
Document Pages : 02
Start time : Aug-31 03:22pm
End time : Aug-31 03:23pm
Pages sent : 02
Job number : 203

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-04n (2000-518XRAB)
Regulated article - Wheat
Destinations - Arizona, Hawaii, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

FAX (636) 737-7085

<http://www.monsanto.com>

January 29, 2001

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (6), (b) (7)(C), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (6), (b) (7)(C) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_006098

2000 Wheat Field Trial Report
USDA # 00-195-04n Monsanto # 2000-518XRAB

Biotech Field Compliance Team
October 11, 2001
Monsanto Company

Location	County	State
Site #1	Yuma	AZ
Site #2	Honolulu	HI

Site 1

Planting Date: December 15, 2000

Harvest Date: May 12, 2001

Destruct Date: July 3, 2001

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

(b) (4)

Site 2

Planting Date: September 7, 2000 and December 15, 2000

Harvest Date: April 16, 2001

Destruct Date: May 31, 2001

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)
(b) (4)

Disposition of the Harvested Material: (b) (4)

Monitoring for Volunteer Plants (b) (4)
(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)
(b) (4)

2000 Wheat Field Trial Report
USDA # 00-195-04n Monsanto # 2000-518XRAB

Biotech Field Compliance Team
October 11, 2001
Monsanto Company

Location	County	State
Site #1	Yuma	AZ
Site #2	Honolulu	HI

Site 1

Planting Date: December 15, 2000

Harvest Date: May 12, 2001

Destruct Date: July 3, 2001

Vector Constructs/Line Numbers Planted: [CBI deleted]

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Site 2

Planting Date: September 7, 2000 and December 15, 2000

Harvest Date: April 16, 2001

Destruct Date: May 31, 2001

Vector Constructs/Line Numbers Planted: [CBI deleted]

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

CONFIDENTIAL

2000 Wheat Field Test Report
USDA #00-195-04n **Monsanto #2000-518XRAB**

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147302522	Yuma	AZ
7683	Honolulu	HI

Yuma County/AZ (2147302522)

(b) (4)

(b) (4)

Honolulu County/HI (7683)

(b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. *National Parks & Conservation Association v. Morton*, 498 F.2d 765, 770 (D.C.Cir. 1974); *Gulf & Western Industries, Inc. v. U.S.*, 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. *Id.* at 530; *National Parks & Conservation Association v. Kleppe*, 547 F.2d 673, 679 (D.C.Cir. 1976); *Miami Herald Pub. Co. v. U.S. Small Business Administration*, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1288 (D.C.Cir. 1983); *Anderson v. Dept. of Health & Human Services*, 907 F.2d 936, 943#44 (10th Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., *Braintree Electric Light Dept. v. Dept. of Energy*, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. *Timken v. U.S. Customs Service*, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., *Teich v. Food & Drug Administration*, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, *Critical Mass Energy Project v. NRC*, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

CBI-DELETED

2000 Wheat Field Test Report
USDA #00-195-04n Monsanto #2000-518XRAB

AMENDED
November 21, 2002

Biotech Field Compliance Team
Monsanto Company

<u>Location</u>	<u>County</u>	<u>State</u>
2147302522	Yuma	AZ
7683	Honolulu	HI

Yuma County/AZ (2147302522)

Planting Date: 12/15/2000

Harvest Date: 05/12/2001

Destruct Date: 07/03/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Honolulu County/HI (7683)

Planting Date: 09/07/2000

Harvest Date: 04/16/2001

Destruct Date: 05/31/2001

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Monitoring for Volunteer Plants: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

7/17/00 11:10 am

Notification Tracking Sheet

=====
Bp number: 00-195-05n
=====

App number: 2000-519XRAB
Received: 7/13/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 8/12/00
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: **(b) (6), (b) (7)(C)**
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: **(b) (6), (b) (7)(C)** Fax: 636-737-7085

- | | Initial | Date |
|--|------------------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apd</i>] | [7/17/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>[initials]</i>]* | [7/17/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLR</i>] | [7/20/00]* |
| 4. <input type="checkbox"/> State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*MN	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*MN	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Release	*HI	*	1*WR *

- | | | |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apd</i>] | [7/17/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLR</i>] | [8/31/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLR</i>] | [9/1/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID
2000-519XRAB

July 12, 2000

Permit Unit
USDA, APHIS, PPQ, BSS
4700 River Rd.
Riverdale, MD 27037

00-195-05n

1. USDA Reference Number
2. Applicant Reference Number 2000-519XRAB
3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

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FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of HJ98, McVey, MN95002, elite lines, and Bobwhite.

CONFIDENTIAL

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 --

(b)(4)

(b)(4)

CBI

Gene: CTP7-CP4 --

(b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b)(4)

(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-519XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 4,000 Kg. of wheat seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MN, MO

DESTINATION:

HI, MN, MO

Ship From:

HI

* [REDACTED] (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: [REDACTED] (b)(4), (b)(7)(C), (b)(6)
Aiea, Oahu, HI, (b)(4), (b)(7)(C), (b)(6) U.S.A., (b)(4), (b)(7)(C), (b)(6)

] - CBI

MN

* [REDACTED] (b)(4) Ramsey County/Province, MN (b)(4) U.S.A.

CONTACT: [REDACTED] (b)(4), (b)(7)(C), (b)(6) MN (b)(4), (b)(7)(C), (b)(6) U.S.A.,
(b)(4), (b)(7)(C), (b)(6)

] - CBI

MO

* [REDACTED] (b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: [REDACTED] (b)(4), (b)(7)(C), (b)(6) MO,
(b)(4), (b)(7)(C), (b)(6) U.S.A., (b)(4), (b)(7)(C), (b)(6)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-519XRAB

Ship To:

HI

*[(b)(4)] Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(7)(C), (b)(6)

(b)(4), (b)(7)(C), (b)(6) HI, (b)(4), (b)(7)(C), (b)(6) U.S.A., (b)(4), (b)(7)(C), (b)(6)

] - CBI

MN

*[(b)(4)] Ramsey County/Province, MN, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(7)(C), (b)(6)

(b)(4), (b)(7)(C), (b)(6) MN, (b)(4), (b)(7)(C), (b)(6) U.S.A.,

] - CBI

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(7)(C), (b)(6)

(b)(4), (b)(7)(C), (b)(6) U.S.A., (b)(4), (b)(7)(C), (b)(6) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-519XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[REDACTED] (b)(4) Honolulu
County/Province, HI, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

[REDACTED] (b)(4), (b)(7)(C), (b)(6)
(b)(4), (b)(7)(C), (b)(6) HI, (b)(4), (b)(7)(C), (b)(6) U.S.A., (b)(4), (b)(7)(C), (b)(6)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-519XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

July 12, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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MONSANTO COMPANY

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CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-519XRAB

July 12, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-195-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-519XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

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FAX

636/737-7085

E-Mail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of HJ98, McVey, MN95002, elite lines, and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4,000 Kg. of wheat seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MN, MO

DESTINATION:

HI, MN, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

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CBI-DELETED

MONSANTO COMPANY

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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-519XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)

Monsanto Company

July 12, 2000

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CHESTERFIELD, MISSOURI 63198

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Monsanto Reference ID

2000-519XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 12, 2000

00-195-05n

1. USDA Reference Number

2. Applicant Reference Number 2000-519XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

EEmail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of HJ98, McVey, MN95002, elite lines, and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

- | | |
|----------------------------------|------------------------------------|
| 7. Mode of Transformation | Disarmed Agrobacterium tumefaciens |
| 8. Introduction | Interstate Movement and Release |

Ship up to 4,000 Kg. of wheat seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MN, MO

DESTINATION:

HI, MN, MO

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-519XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-519XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (7)(C), (b) (6)



Monsanto Company

July 12, 2000

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006136

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

July 17, 2000

Dear Dr. Hanks:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006137

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006138



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

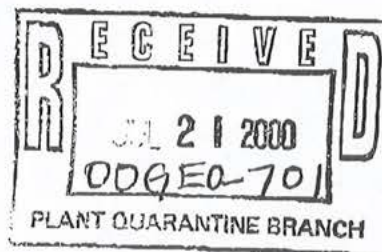
Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (7)(C), (b) (6)

Date: 30 August 2000

State: Hawaii

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

faxed 7-24-00

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

July 17, 2000

Dear Dr. Hanks:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (7)(C), (b) (6)

Date: 7-24-00

State: MN

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-05n	Applicant #:	2000-519XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MN MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (7)(C), (b) (6)

Date: 7-24-00

State: MO

Rptloc01/R4

JUL 25 2000



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OR120018_BR_006141

314751005 P.03/08

DEPT OF AGRICULTURE

JUL-25-2000 10:09

August 31, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-05n (2000-519XRAB)
Regulated article - Wheat
Destinations - Hawaii, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.

OR120018_BR_006142

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
S. Wood, PPQ, NER, Raleigh, NC
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-195-05n

Confirmation Report-Memory Send

Time : Aug-31-00 03:21pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 201
Date : Aug-31 03:19pm
To : 916367377085
Document Pages : 02
Start time : Aug-31 03:19pm
End time : Aug-31 03:21pm
Pages sent : 02
Job number : 201

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-05n (2000-519XRAB)
Regulated article - Wheat
Destinations - Hawaii, Minnesota, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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OR120018_BR_006144

MONSANTO

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January 29, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (7)(C), (b) (6), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (7)(C), (b) (6) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (7)(C), (b) (6)

Sincerely,

(b) (7)(C), (b) (6)

2000 Wheat Field Trial Report
USDA # 00-195-05n Monsanto # 2000-519XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Honolulu

State
HI

Site 1

Planting Date: September 7, 2000; December 15, 2000

Harvest Date: April 16, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391; PV-TXGT12 line 33512

Purpose of Trial: (b) (4)

Field Monitoring for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: (b) (4)
(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)
(b) (4)

Disposition of the Harvested Material: (b) (4)

Monitoring for Volunteer Plants: (b) (4)
(b) (4)

2000 Wheat Field Trial Report
USDA # 00-195-05n Monsanto # 2000-519XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Honolulu

State
HI

Site 1

Planting Date: September 7, 2000; December 15, 2000

Harvest Date: April 16, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10 line 33391; PV-TXGT12 line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (7)(C), (b) (6)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (7)(C), (b) (6)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-06n (2000-520XPAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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OR120018_BR_006148

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

(b) (7)(C), (b) (6)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

July 12, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number

2. Applicant Reference Number 2000-520XRAB

3. Applicant/Responsible Party

(b) (7)(C), (b) (6)

Phone

(b) (7)(C), (b) (6)

FAX

636/737-7085

E-Mail

(b) (7)(C), (b) (6)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of Oxen, Ingot, SD3407, elite lines and Bobwhite.

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b)(4)

CBI

(b)(4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- (b)(4)

(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 (b)(4)

(b)(4)

CBI

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Monsanto Reference ID

2000-520XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 4,000 kg. of wheat seed, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, SD

DESTINATION:

HI, MO, SD

Ship From:

HI

*[(b)(4) (b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

SD

*[(b)(4) Brookings County/Province, SD, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD, (b)(4), (b)(6), (b)(7)(C)
U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

Ship To:

HI

*[(b)(4)] Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

MO

*[(b)(4)] St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

SD

*[(b)(4)] Brookings County/Province, SD, (b)(4)
U.S.A.

CONTACT: (b)(4), (b)(6), (b)(7)(C) SD, (b)(4), (b)(6), (b)(7)(C)
U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

(b)(4) Honolulu
County/Province, HI, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(4), (b)(6), (b)(7)(C)
(b)(4), (b)(6), (b)(7)(C) HI, (b)(4), (b)(6), (b)(7)(C) U.S.A., (b)(4), (b)(6), (b)(7)(C)

] - CBI

MONSANTO

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b)(4)

Monsanto Company

July 12, 2000

MONSANTO



April 4, 2002

Attn: Mary Jackson
Regulatory Analyst
Animal and Plant Inspection Services
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Reference: Submission of Final Test Reports

Dear Mary,

The following USDA field releases have been completed and we are now submitting final reports required by the notifications. Please find the final reports for the following USDA notifications enclosed.

Monsanto ID#	USDA #	Crop
2000-328XRAB	00-089-12N	COTTON
2000-534XRAB	00-222-01N	WHEAT
2000-171XRAB	00-054-07N	WHEAT
2000-125XRAB	00-046-09N	WHEAT
2000-164XRAB	00-062-03N	WHEAT
2000-83XRAB	00-039-05N	WHEAT
2000-536XRAB	00-236-01N	WHEAT
2000-109XRAB	00-041-04N	WHEAT
2000-568XRAB	00-231-09N	WHEAT
2000-522XRAB	00-199-02N	WHEAT
2000-90XRAB	00-039-11N	WHEAT
2000-519XRAB	00-195-05N	WHEAT
2000-127XRAB	00-046-11N	WHEAT
2000-521XRAB	00-199-01N	WHEAT
2000-520XRAB	00-195-06N	WHEAT
2000-518XRAB	00-195-04N	WHEAT
2000-661XRAB	00-297-02N	WHEAT
2000-580XRAB	00-243-05N	WHEAT

Sincerely,

(b) (4), (b) (6), (b) (7)(C)

CONFIDENTIAL

2000 Wheat Field Trial Report
USDA # 00-195-06n Monsanto # 2000-520XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site # 1

County
Honolulu

State
HI

Site 1

(b) (4)

Site 1

(b) (4)

(b) (4)

7/17/00 11:10 am

Notification Tracking Sheet

=====

Bp number: 00-195-06n

=====

App number: 2000-520XRAB Begin movement: 8/11/00
 Received: 7/13/00 End movement: 8/11/01
 Institution: Monsanto Begin release: 8/11/00
 Recipient: Wheat End release: 8/11/01
 Status: Pending Acre: 2.00
 Effective date: 8/12/00 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

- | | Initial | Date |
|--|----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>ajd</i>] | [7/17/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>J</i>]* | [7/17/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLH</i>] | [7/20/00]* |
| 4. [] State response | | |

	O/d	Loc	Site	Reg
Interstate	*Dest*	HI	*	*WR *
Interstate	*Dest*	MO	*	*SCR *
Interstate	*Dest*	SD	*	*SCR *
Interstate	*Orig*	HI	*	*WR *
Interstate	*Orig*	MO	*	*SCR *
Interstate	*Orig*	SD	*	*SCR *
Release	*	*HI	*	1*WR *

- | | Initial | Date |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>ajd</i>] | [7/17/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLH</i>] | [8/31/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLH</i>] | [9/1/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

July 12, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-195-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-520XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of Oxen, Ingot, SD3407, elite lines and Bobwhite.

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMeVa/l2 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

(b) (4)

BI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/5 -

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 --

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 4,000 kg. of wheat seed, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, SD

DESTINATION:

HI, MO, SD

Ship From:

HI

*[REDACTED] (b) (4) Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

SD

*[REDACTED] (b) (4) Brookings County/Province, SD (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

U.S.A., (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

Ship To:

HI

*[(b) (4) Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

SD

*[(b) (4) Brookings County/Province, SD (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-520XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[(b) (4) Honolulu
County/Province, HI, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 12, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 12, 2000

00-195-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-520XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of Oxen, Ingot, SD3407, elite lines and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 4,000 kg. of wheat seed, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, SD

DESTINATION:

HI, MO, SD

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 12, 2000

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 12, 2000

00-195-06n

1. USDA Reference Number

2. Applicant Reference Number 2000-520XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

August 11, 2000 - August 11, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate Tolerant

Cultivar/Variety Backcross progenies of Oxen, Ingot, SD3407, elite lines and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 4,000 kg. of wheat seed, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, SD

DESTINATION:

HI, MO, SD

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

SD

[CBI Deleted] -- *Brookings County/Province, SD, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-520XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

MONSANTO

Food • Health • Hope



CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-520XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 12, 2000

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006186

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006187

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

July 17, 2000

Dear Mr. Fridley:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006188



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

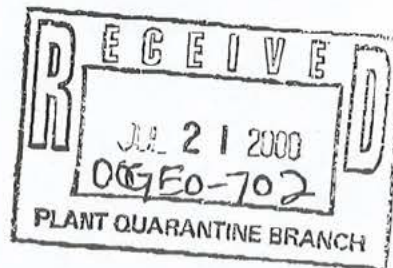
Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

- X ☐ State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
- ☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 30 August 2000

State: Hawaii

Rptloc01/R4



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OR120018_BR_006189

AUG 31 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael E. Brown

Signature: (b) (6), (b) (7)(C)

Date: 7-24-00

State: MO

Rptloc01/R4

JUL 25 2000



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3147510005 P.05/08

DEPT OF AGRICULTURE

JUL-25-2000 10:09



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

July 17, 2000

Dear Mr. Fridley:

Enclosed is notification 00-195-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-195-06n	Applicant #:	2000-520XRAB
Received:	July 13, 2000	Effective:	August 12, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO SD		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO



STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 7/26/00

State: South Dakota

RptLoc01/R4



JUL 28 2000

August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear **(b) (6), (b) (7)(C)**

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-06n (2000-520XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.

OR120018_BR_006192

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-195-06n

Confirmation Report-Memory Send

Time : Aug-31-00 03:22pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 202
Date : Aug-31 03:20pm
To : 916367377085
Document Pages : 02
Start time : Aug-31 03:21pm
End time : Aug-31 03:22pm
Pages sent : 02
Job number : 202

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (6), (b) (7)(C)

700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-195-06n (2000-520XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri, South Dakota

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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An Equal Opportunity Employer

OR120018_BR_006194

MONSANTO

Food • Health • Hope



January 29, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (6), (b) (7)(C), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (6), (b) (7)(C) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

7/17/00 11:10 am

Notification Tracking Sheet

=====

Bp number: 00-199-01n

=====

App number: 2000-521XRAB
Received: 7/17/00
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: ~~7/17/00~~ 8/16/2000
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C)
Begin movement: 8/12/00
End movement: 8/12/01
Begin release: 8/12/00
End release: 8/12/01
Acre: 2.00
CBI status: CBI
Fax: 636-737-7085

- | | Initial | Date |
|--|---------|---------------|
| 1. [✓] Assign Bp number and initial data entry | [ajb] | [7/17/2000] |
| 2. [✓] Review by biotechnologist | []* | [7/17/00]* |
| 3. [✓] Letter of notification to State Fed-ex | [KLO] | [7/20/00]* |
| 4. [] State response | | |

O/d	Loc	Site	Reg
Interstate	*Dest*HI	*	*WR *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Dest*MT	*	*WR *
Interstate	*Orig*HI	*	*WR *
Interstate	*Orig*MO	*	*SCR *
Interstate	*Orig*MT	*	*WR *
Release	* *HI	*	1*WR *

- | | | |
|--|---------|---------------|
| 5. [✓] Enter genes into database | [ajb] | [7/17/2000] |
| 6. [✓] Letter of acknowledgement/denial/withdraw | [KLO] | [8/31/00]* |
| 7. [✓] Enter final data into database | [KLO] | [9/1/00] |

MONSANTO

Food • Health • Hope



CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-521XRAB

July 13, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-199-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-521XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of McNeal, MT9433, MT9653, MTHW9701, elite lines and Bobwhite

CONFIDENTIAL

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

CBI

(b) (4)

Gene: CTP7-CP4 --

(b) (4)

CBI

(b) (4)

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

(b) (4)

CONFIDENTIAL

Monsanto Reference ID

2000-521XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 kg. seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, MT

DESTINATION:

HI, MO, MT

Ship From:

HI

* [REDACTED] (b) (4) Honolulu
County/Province, HI (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) HI (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

MO,

] - CBI

MT

* [REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

MT, (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-521XRAB

Ship To:

HI

*[REDACTED] (b) (4) Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[REDACTED] (b) (4) St. Louis County/Province, MO (b) (4)
U.S.A.

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MT

*[REDACTED] (b) (4) Gallatin County/Province, MT, (b) (4)

CONTACT: [REDACTED] (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-521XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

(b) (4) Honolulu
County/Province, HI, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-521XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 13, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-521XRAB

July 13, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-199-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-521XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of McNeal, MT9433, MT9653, MTHW9701, elite lines and Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

- 7. Mode of Transformation** Disarmed Agrobacterium tumefaciens
- 8. Introduction** Interstate Movement and Release

Ship up to 4000 kg. seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, MT

DESTINATION:

HI, MO, MT

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

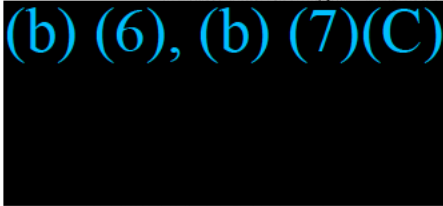
Monsanto Reference ID

2000-521XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 13, 2000

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-521XRAB

July 13, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-199-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-521XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of McNeal, MT9433, MT9653, MTHW9701, elite lines and Bobwhite

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/l2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/l5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 4000 kg. seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

HI, MO, MT

DESTINATION:

HI, MO, MT

Ship From:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

Ship To:

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

MT

[CBI Deleted] -- *Gallatin County/Province, MT

CBI-DELETED

Monsanto Reference ID

2000-521XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 2 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, Missouri 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

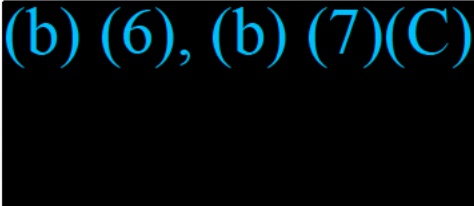
Monsanto Reference ID

2000-521XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 13, 2000

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006222

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
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Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006223

file copy

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

July 17, 2000

Dear Dr. Gingery:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
Release destination:	HI		

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Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006224



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

By number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

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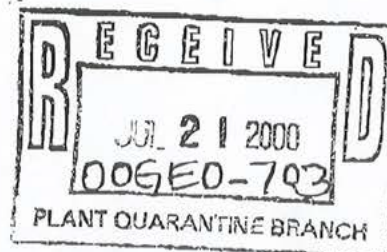
Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 30 August 2000

State: Hawaii

Rpt10c01/R4



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OR120018_BR_006225

AUG 31 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MO 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

7/24/00

State:

MO

Rptloc01/R4

JUL 25 2000



APHIS - Protecting American Agriculture

OR120018_BR_000228

314751005 P.06/08

DEPT OF AGRICULTURE

JUL-25-2000 10:09



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Gary Gingery, Administrator
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

July 17, 2000

Dear Dr. Gingery:

Enclosed is notification 00-199-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-01n	Applicant #:	2000-521XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	HI MO MT		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori M. Witham

Signature: (b) (6), (b) (7)(C)

Date: 7/21/00

State: Montana

Rptloc01/R4



August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-199-01n (2000-521XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.

OR120018_BR_006228

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
G. Gingery, Montana Dept. of Agric., Helena, MT
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO

File number 00-199-01n

Confirmation Report-Memory Send

Time : Aug-31-00 03:26pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 205
Date : Aug-31 03:24pm
To : 916367377085
Document Pages : 02
Start time : Aug-31 03:25pm
End time : Aug-31 03:26pm
Pages sent : 02
Job number : 205

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-199-01n (2000-521XRAB)
Regulated article - Wheat
Destinations - Hawaii, Missouri, Montana

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

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 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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January 29, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (6), (b) (7)(C), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (6), (b) (7)(C) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_006231

2000 Wheat Field Trial Report
USDA # 00-199-01n Monsanto # 2000-521XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Honolulu

State
HI

Site 1

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-199-01n Monsanto # 2000-521XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Honolulu

State
HI

Site 1

Planting Date: September 7, 2000; December 15, 2000

Harvest Date: April 5, 2001

Vector Constructs/Line Numbers Planted: [CBI deleted]

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteer Plants: [CBI deleted]

7/17/00 11:10 am

Notification Tracking Sheet

=====

Bp number: 00-199-02n

=====

App number: 2000-522XRAB Begin movement: 8/12/00
 Received: 7/17/00 End movement: 8/12/01
 Institution: Monsanto Begin release: 8/12/00
 Recipient: Wheat End release: 8/12/01
 Status: Pending Acre: 6.00
 Effective date: ~~8/12/00~~ 8/16/2000 CBI status: CBI
 Phenotype: HT - Glyphosate tolerant
 Comments:
 Resp person: (b) (6), (b) (7)(C)
 Parsed name:
 Address1: Monsanto Company
 Address2: 700 Chesterfield Parkway N.
 Address3:
 Address4:
 City/State/Zip: Chesterfield, MO 63198
 Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

=====

- | | Initial | Date |
|--|----------------|---------------|
| 1. <input checked="" type="checkbox"/> Assign Bp number and initial data entry | [<i>apd</i>] | [7/17/2000] |
| 2. <input checked="" type="checkbox"/> Review by biotechnologist | [<i>/</i>]* | [7/17/00]* |
| 3. <input checked="" type="checkbox"/> Letter of notification to State <i>Fed-ex</i> | [<i>KLO</i>] | [7/20/00]* |
| 4. <input type="checkbox"/> State response | | |

	O/d	Loc	Site	Reg		
Interstate *Dest*	AZ	*		*WR	*	[]
Interstate *Dest*	HI	*		*WR	*	[]
Interstate *Dest*	MO	*		*SCR	*	[]
Interstate *Orig*	AZ	*		*WR	*	
Interstate *Orig*	HI	*		*WR	*	
Interstate *Orig*	MO	*		*SCR	*	
Release *	HI	*		1*WR	*	[]

- | | | |
|--|----------------|---------------|
| 5. <input checked="" type="checkbox"/> Enter genes into database | [<i>apd</i>] | [7/17/2000] |
| 6. <input checked="" type="checkbox"/> Letter of <u>acknowledgement</u> /denial/withdraw | [<i>KLO</i>] | [8/31/00]* |
| 7. <input checked="" type="checkbox"/> Enter final data into database | [<i>KLO</i>] | [9/1/00] |

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 13, 2000

1. USDA Reference Number

00-199-02N

2. Applicant Reference Number 2000-522XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BW251, BW252, elite lines and Bobwhite.

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [REDACTED] (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [REDACTED] (b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 --

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 --

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 --

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens
8. Introduction Interstate Movement and Release

Ship up to 20,000 kg. of seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:
AZ, HI, MO

DESTINATION:
AZ, HI, MO

Ship From:

AZ

*[(b) (4)] Yuma County/Province, AZ, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

HI

*[(b) (4)]
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

Ship To:

AZ

*[(b) (4)] Yuma County/Province, AZ, (b) (4)

CONTACT: (b) (4), (b) (6), (b) (7)(C) AZ,
(b) (4), (b) (6), (b) (7)(C)

] - CBI

HI

*[(b) (4)] Honolulu
County/Province, HI, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4)] St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[REDACTED] (b) (4) Honolulu
County/Province, HI, U.S.A., 6 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
[REDACTED] (b) (4), (b) (6), (b) (7)(C) HI, S [REDACTED] (b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED] (b) (4), (b) (6), (b) (7)(C)

] - CBI

MONSANTO

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CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 13, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

July 13, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number

00-199-02N

2. Applicant Reference Number 2000-522XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BW251, BW252, elite lines and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

7. Mode of Transformation

Disarmed *Agrobacterium tumefaciens*

8. Introduction

Interstate Movement and Release

Ship up to 20,000 kg. of seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

AZ, HI, MO

DESTINATION:

AZ, HI, MO

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 6 acres

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

July 13, 2000

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

July 13, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number

00-199-020

2. Applicant Reference Number 2000-522XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

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636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BW251, BW252, elite lines and Bobwhite.

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 -- (b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 -- (b)(4)

(b)(4)

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 20,000 kg. of seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

AZ, HI, MO

DESTINATION:

AZ, HI, MO

Ship From:

AZ

*[(b)(4) Yuma County/Province, AZ (b)(4)

CONTACT: (b)(6), (b)(4), (b)(7)(C) AZ,
(b)(6), (b)(4), (b)(7)(C)

] - CBI

HI

*[(b)(4) Honolulu
County/Province, HI (b)(4) U.S.A.

CONTACT: (b)(6), (b)(4), (b)(7)(C)
(b)(6), (b)(4), (b)(7)(C) HI, (b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO (b)(4)
U.S.A.

CONTACT: (b)(6), (b)(4), (b)(7)(C)
(b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C) MO,

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

Ship To:

AZ

*[(b)(4) Yuma County/Province, AZ, (b)(4)

CONTACT: (b)(6), (b)(4), (b)(7)(C) AZ,
(b)(6), (b)(4), (b)(7)(C)

] - CBI

HI

*[(b)(4) Honolulu
County/Province, HI, (b)(4) U.S.A.

CONTACT: (b)(6), (b)(4), (b)(7)(C)
(b)(6), (b)(4), (b)(7)(C) HI, (b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

MO

*[(b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b)(6), (b)(4), (b)(7)(C) MO,
(b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-522XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

(b)(4) Honolulu
County/Province, HI, U.S.A., 6 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b)(6), (b)(4), (b)(7)(C)
HI, (b)(6), (b)(4), (b)(7)(C) U.S.A., (b)(6), (b)(4), (b)(7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

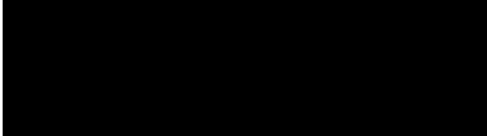
Monsanto Reference ID

2000-522XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 13, 2000

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MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

July 13, 2000

1. USDA Reference Number

00-199-02N

2. Applicant Reference Number 2000-522XRAB

3. Applicant/Responsible Party

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Email

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

August 12, 2000 - August 12, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar/Variety Backcross progenies of BW251, BW252, elite lines and Bobwhite.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

7. Mode of Transformation

Disarmed Agrobacterium tumefaciens

8. Introduction

Interstate Movement and Release

Ship up to 20,000 kg. of seeds, seedlings, and leaf tissue to and from each location.

ORIGIN:

AZ, HI, MO

DESTINATION:

AZ, HI, MO

Ship From:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

Ship To:

AZ

[CBI Deleted] -- *Yuma County/Province, AZ

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-522XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

HI (1)

HI

[CBI Deleted] -- Honolulu County/Province, HI, U.S.A., 6 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-522XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

July 13, 2000

file copy

Dr. Scott Sobey, Associate Director
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

July 17, 2000

Dear Dr. Sobey:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-02n	Applicant #:	2000-522XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006270

file copy

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-02n	Applicant #:	2000-522XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006271

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-02n	Applicant #:	2000-522XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006272

Not a FOIA Deletion

OR120018_BR_006273



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Dr. Scott Sobey, ~~Associate Director~~
Arizona Department of Agriculture
1688 W. Adams
Phoenix, AZ 85007

July 17, 2000

Dear Dr. Sobey:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-02n	Applicant #:	2000-522XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

S. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: G. John Caravetta

Signature: (b) (6), (b) (7)(C)

Date: 7/28/00

State: Arizona

Rptloc01/R4



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OR120018_BR_006274

JUL 31 2000

TOTAL P.02



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Myron Isherwood Jr., Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
701 Ilalo Street
Honolulu, HI 96813

July 17, 2000

Dear Mr. Isherwood Jr.:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Sp number 00-199-02n
Received: July 14, 2000
Institution: Monsanto
Interstate destination: AZ HI MO
Release destination: HI

Applicant #: 2000-522XRAB
Effective: August 13, 2000
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

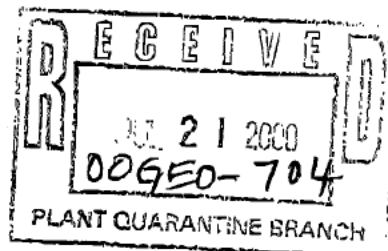
Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Sacramento, CA



STATE RESPONSE TO NOTIFICATION

 X State concurs with APHIS determination. Please notify Ms. Carol Okada,
Hawaii Dept. of Agriculture, 701 Ilalo St., Honolulu, HI 96813.
 State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. OkadaSignature: (b) (6), (b) (7)(C)Date: 30 August 2000State: Hawaii

Rptloc01/R4





United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

July 17, 2000

Dear Mr. Brown:

Enclosed is notification 00-199-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-199-02n	Applicant #:	2000-522XRAB
Received:	July 14, 2000	Effective:	August 13, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	AZ HI MO		
Release destination:	HI		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Dr. Elaine Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

Y State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official: Michael Brown

Signature: (b) (6), (b) (7)(C)

Date: 7/24/00

State: MO

Rptloc01/R4



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JUL 25 2000

August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-199-02n (2000-522XRAB)
Regulated article - Wheat
Destinations - Arizona, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.

OR120018_BR_006277

- b) Pollen movement and viability under island's climatic conditions, and any occurrence of introduced traits transferred to non-test plants.

The report should be submitted to the Plant Quarantine Branch, 701 Ilalo Street, Honolulu, Hawaii, 96813, with a copy to Ms. Carol Okada, within six months of completion or termination of the test.

4. The introduction of any organism other than wheat seeds may be regulated by the Plant Quarantine Branch. For more information on the organisms regulated by the Branch, please contact Mr. Myron Isherwood Jr., Hawaii Department of Agriculture.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Biotechnology Evaluations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:

S. Sobey, Arizona Dept. of Agric., Phoenix, AZ
M. Isherwood, Hawaii Dept. of Agric., Honolulu, HI
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
R. Stoaks, PPQ, WR, Sacramento, CA
D. DeWeese, PPQ, SCR, Jefferson City, MO
File number 00-199-02n

Not a FOIA Deletion

Confirmation Report-Memory Send

Time : Aug-31-00 03:25pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 204
Date : Aug-31 03:23pm
To : 916367377085
Document Pages : 02
Start time : Aug-31 03:23pm
End time : Aug-31 03:25pm
Pages sent : 02
Job number : 204

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

August 31, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after August 31, 2000.

Interstate movement and Release
Notification no. 00-199-02n (2000-522XRAB)
Regulated article - Wheat
Destinations - Arizona, Hawaii, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Hawaii has requested that you adhere to the following requirements:

1. The field should remain fallow for a minimum of thirty days. During the fallow period, the field should be watered by overhead irrigation to allow the germination of volunteer wheat. Volunteer wheat should be destroyed.
2. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 701 Ilalo Street, Honolulu, Hawaii 96813, at each of the following times:
 - a) All planting, pollinating and harvesting dates of each field trial.
 - b) Any changes to the field sites, recommended conditions, or other related matters.
 - c) The unplanned release or theft of any transgenic wheat plants or plant parts.
3. Submit a written report on the field test data including information on:
 - a) The germination of volunteer wheat after harvest.



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OR120018_BR_006280

Not a FOIA Deletion

MONSANTO

Food • Health • Hope



January 29, 2001

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
PHONE (314) 694-1000
FAX (636) 737-7085
<http://www.monsanto.com>

Ms. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology and Scientific Services
4700 River Road, Unit 147
Riverdale, MD

Dear Ms. Hatmaker:

The responsible researcher at Hawaii Agriculture Research Center has changed for the following wheat notifications.

USDA #	Monsanto #	Change
00-195-04n	2000-518XRAB	(b) (6), (b) (7)(C), (b) (4)
00-195-05n	2000-519XRAB	
00-195-06n	2000-520XRAB	
00-199-01n	2000-521XRAB	
00-199-02n	2000-522XRAB	
00-297-02n	2000-661XRAB	

To (b) (6), (b) (7)(C) phone 808/486-5020 fax. If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_006282

2000 Wheat Field Trial Report
USDA # 00-199-02n Monsanto # 2000-522XRAB

Biotech Field Compliance Team
October 18, 2001
Monsanto Company

Location	County	State
Site 1	Honolulu	HI

Site 1

Planting Date: December 5, December 7 and December 15, 2000

Harvest Date: May 17, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391; PV-TXGT12, line 33512

Purpose of Trial: [CBI deleted]

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Disposition of the Harvested Material: [CBI deleted]

Monitoring for Volunteers: [CBI deleted]

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2000 Wheat Field Trial Report
USDA # 00-199-02n Monsanto # 2000-522XRAB

Biotech Field Compliance Team
October 18, 2001
Monsanto Company

Location
Site 1

County
Honolulu

State
HI

Site 1

(b) (4)

8/10/00 7:34 am

Notification Tracking Sheet

=====
Bp number: 00-222-01n
=====

App number: 2000-534XRAB Begin movement: 9/07/00
Received: 8/09/00 End movement: 9/07/01
Institution: Monsanto Begin release: 9/07/00
Recipient: Wheat End release: 9/07/01
Status: Pending Acre: 2.00
Effective date: 9/08/00 CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway N.
Address3:
Address4:
City/State/Zip: Chesterfield, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085
=====

	Initial	Date
1. [✓] Assign Bp number and initial data entry	[ajd]	[8/10/2000]
2. [✓] Review by biotechnologist	[AMK]*	[8/10/2000]
3. [✓] Letter of notification to State Fed-ex	[KLR]	[8/11/00]*
4. [] State response		

O/d	Loc	Site	Reg
Interstate	*Dest*IL	*	*NER *
Interstate	*Dest*MO	*	*SCR *
Interstate	*Orig*IL	*	*NER *
Interstate	*Orig*MO	*	*SCR *
Release	*IL	*	1*NER *

5. [✓] Enter genes into database	[ajd]	[8/10/2000]
6. [✓] Letter of <u>acknowledgement</u> /denial/withdraw	[KLR]	[9/5/00]*
7. [✓] Enter final data into database	[KLR]	[9/6/00]

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-534XRAB

August 08, 2000

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

00-222-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-534XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

E-Mail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 07, 2000 - September 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate - tolerant

Cultivar variety: Bobwhite and backcross- derived progenies of winter wheat

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 --

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP7-CP4 -- [

(b) (4)

(b) (4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [

(b) (4)

(b) (4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [

(b) (4)

(b) (4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 400kg of seeds, seedlings and leaf tissues to and from each location.

ORIGIN:

IL, MO

DESTINATION:

IL, MO

Ship From:

IL

* [REDACTED] (b) (4) Jersey County/Province, IL, (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) IL,
(b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED]

] - CBI

MO

* [REDACTED] (b) (4) St. Louis County/Province, MO (b) (4) U.S.A.

CONTACT:

(b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., [REDACTED]

] - CBI

Ship To:

IL

* [REDACTED] (b) (4) Jersey County/Province, IL, (b) (4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) IL,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

IL (1)

IL

[(b) (4) Jersey County/Province, IL, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) IL, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

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CONFIDENTIAL

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

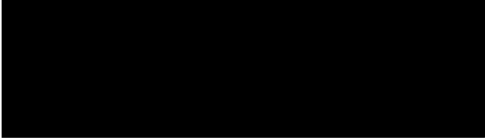
Monsanto Reference ID

2000-534XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 08, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

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NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-534XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

August 08, 2000

00-222-01n

1. USDA Reference Number

2. Applicant Reference Number 2000-534XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone

(b) (6), (b) (7)(C)

FAX

636/737-7085

EMail

(b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway North

St. Louis

MO

63198

4. Duration of Introduction

Interstate Movement and Release

September 07, 2000 - September 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate - tolerant

Cultivar variety: Bobwhite and backcross- derived progenies of winter wheat

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 400kg of seeds, seedlings and leaf tissues to and from each location.

ORIGIN:

IL, MO

DESTINATION:

IL, MO

Ship From:

IL

[CBI Deleted] -- *Jersey County/Province, IL, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

IL

[CBI Deleted] -- *Jersey County/Province, IL, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

IL (1)

IL

[CBI Deleted] -- Jersey County/Province, IL, U.S.A., 2 acres

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CBI-DELETED

MONSANTO COMPANY

700 CHESTERFIELD PKWY NORTH

CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

Monsanto Reference ID

2000-534XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

August 08, 2000

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CONFIDENTIAL

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Interstate Movement and Release

September 07, 2000 - September 07, 2001

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: glyphosate - tolerant

Cultivar variety: Bobwhite and backcross- derived progenies of winter wheat

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/12 --

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/15 --

(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/15 -- (b)(4)
(b)(4)

CBI

Gene: CTP7-CP4 -- (b)(4)
(b)(4)

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- (b)(4)
(b)(4)

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- (b)(4)
(b)(4)

CBI

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 400kg of seeds, seedlings and leaf tissues to and from each location.

ORIGIN:

IL, MO

DESTINATION:

IL, MO

Ship From:

IL

* [REDACTED] (b)(4) Jersey County/Province, IL (b)(4) U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C) IL,
(b)(4), (b)(6), (b)(7)(C) U.S.A., [REDACTED]

] - CBI

MO

* [REDACTED] (b)(4) St. Louis County/Province, MO, (b)(4) U.S.A.

CONTACT:

(b)(4), (b)(6), (b)(7)(C) St. Louis, MO,
(b)(4), (b)(6), (b)(7)(C) U.S.A., [REDACTED]

] - CBI

Ship To:

IL

* [REDACTED] (b)(4) Jersey County/Province, IL, (b)(4) U.S.A.

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C) IL,
(b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

MO

* (b)(4) St. Louis County/Province, MO, (b)(4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

] - CBI

CONFIDENTIAL

Monsanto Reference ID

2000-534XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

IL (1)

IL

(b)(4)

Jersey County/Province, IL, U.S.A., 2 acres.

RESPONSIBLE PERSON/RESEARCHER:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) IL, 62052, U.S.A. (b) (4), (b) (6), (b) (7)(C)

] - CBI

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MONSANTO COMPANY

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I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)



Monsanto Company

August 08, 2000

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.¹

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of transgenic crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

¹ In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Rhone-Poulenc, Zeneca, and Ciba.

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Interstate Movement and Release

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Wheat, Triticum aestivum

6. Regulated Article

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Cultivar variety: Bobwhite and backcross- derived progenies of winter wheat

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

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Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

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GENE OF INTEREST

Promoter: CMP3/I5 -- [CBI Deleted]

CBI

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CBI-DELETED

Monsanto Reference ID

2000-534XRAB

designation of transformed line: 33512

Constructs: PV-TXGT12

GENE OF INTEREST

Promoter: CMP 3/I5 -- [CBI Deleted]

CBI

Gene: CTP7-CP4 -- [CBI Deleted]

CBI

Terminator: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of *Agrobacterium tumefaciens* T-DNA.

GENE OF INTEREST

Promoter: MP4 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species, strain CP4.

Terminator: M1 -- [CBI Deleted]

CBI

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

7. Mode of Transformation Disarmed Agrobacterium tumefaciens

8. Introduction Interstate Movement and Release

Ship up to 400kg of seeds, seedlings and leaf tissues to and from each location.

ORIGIN:

IL, MO

DESTINATION:

IL, MO

Ship From:

IL

[CBI Deleted] -- *Jersey County/Province, IL, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

Ship To:

IL

[CBI Deleted] -- *Jersey County/Province, IL, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

MO

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

CBI-DELETED

Monsanto Reference ID

2000-534XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

IL (1)

IL

[CBI Deleted] -- Jersey County/Province, IL, U.S.A., 2 acres

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CBI-DELETED

Monsanto Reference ID
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CHESTERFIELD, MISSOURI 63198

PHONE (314) 694-1000

<http://www.monsanto.com>

9. Certification

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(b) (6), (b) (7)(C)

Monsanto Company
August 08, 2000



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Stanley E. Smith, Plant & Pesticide Spec. Supervisor
Illinois Department of Agriculture
CMS North Suburban
9511 Harrison Street, Room A169
Des Plaines, IL 60016

August 10, 2000

Dear Mr. Smith:

Enclosed is notification 00-222-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 00-222-01n

Applicant #: 2000-534XRAB

Received: August 9, 2000

Effective: September 8, 2000

Institution: Monsanto

Recipient: Wheat

Interstate destination: IL MO

Release destination: IL

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimile (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Ratmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

☒ State concurs with APHIS determination.

☐ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

(b) (6), (b) (7)(C)

Date: 8-21-00

State: IL

Rptloc01/R4

AUG 22 2000



APHIS - Protecting American Agriculture

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OR120018_BR_006322

Aug. 22 2000 09:33AM P2

FAX NO. : 847 294 4350

FROM : ID04 DES PLAINES

file copy

Mr. Stanley E. Smith, Plant & Pesticide Spec. Supervisor
Illinois Department of Agriculture
CMS North Suburban
9511 Harrison Street, Room A169
Des Plaines, IL 60016

August 10, 2000

Dear Mr. Smith:

Enclosed is notification 00-222-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-222-01n	Applicant #:	2000-534XRAB
Received:	August 9, 2000	Effective:	September 8, 2000
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	IL MO		
Release destination:	IL		

Should you have comments, please respond either by telephone (301) 734-5787 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: S. Wood, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006323



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 10, 2000

Dear Mr. Brown:

Enclosed is notification 00-222-01n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	00-222-01n	Applicant #:	2000-S34XRAB
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Sincerely,

(b) (6), (b) (7)(C)

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

X

State concurs with APHIS determination.

State DOES NOT CONCUR and offers the following reasons:

Name of State official:

Michael E. Brown

Signature:

(b) (6), (b) (7)(C)

Date:

8/21/00

State:

MO,

Rptloc01/R4

AUG 22 2000



APHIS - Protecting American Agriculture

OR120018_BR_006324

P.01/02 314751005

DEPT OF AGRICULTURE

AUG-22-2000 11:45

file copy

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

August 10, 2000

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E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: D. DeWeese, PPQ, Jefferson City, MO

STATE RESPONSE TO NOTIFICATION

_____ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: _____

Date: _____

State: _____

Rptloc01/R4

OR120018_BR_006325

September 5, 2000

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Pkwy N
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after September 8, 2000.

Interstate movement and Release
Notification no. 00-222-01n (2000-534XRAB)
Regulated article - Wheat
Destinations - Illinois, Missouri

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials, and the Regional Program Managers, (Biotechnology).

Sincerely,

/s/ E. Dianne Hatmaker

E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

CC:

S. Smith, Illinois Dept. of Agric., Des Plaines, IL
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
S. Wood, PPQ, NER, Raleigh, NC
File number 00-222-01n

OR120018_BR_006326

Confirmation Report-Memory Send

Time : Sep-05-00 04:11pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 239
Date : Sep-05 04:10pm
To : 916367377085
Document Pages : 01
Start time : Sep-05 04:11pm
End time : Sep-05 04:11pm
Pages sent : 01
Job number : 239

*** SEND SUCCESSFUL ***



United States
Department of
Agriculture

Animal and
Plant Health
Inspection Service

4700 River Road
Riverdale, MD 20737

September 5, 2000

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Destinations - Illinois, Missouri

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Sincerely,

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E. Dianne Hatmaker, Chief
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc:
S. Smith, Illinois Dept. of Agric., Des Plaines, IL
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. DeWeese, PPQ, SCR, Jefferson City, MO
S. Wood, PPQ, NER, Raleigh, NC



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An Equal Opportunity Employer

OR120018_BR_006327

2000 Wheat Field Trial Report
USDA # 00-222-01n Monsanto # 2000-534XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Jersey

State
IL

Jersey County, IL

Planting Date: October 9, 2000

Destruct Date: June 18, 2001

Vector Constructs/Line Numbers Planted: PV-TXGT10, line 33391

Purpose of Trial:

(b) (4)

Field Monitoring for Disease Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Insect Susceptibility:

(b) (4)

(b) (4)

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics:

(b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting:

(b) (4)

(b) (4)

Additional Comments:

(b) (4)

(b) (4)

2000 Wheat Field Trial Report
USDA # 00-222-01n Monsanto # 2000-534XRAB

Biotech Field Compliance Team
October 15, 2001
Monsanto Company

Location
Site #1

County
Jersey

State
IL

Jersey County, IL

Planting Date: October 9, 2000

Destruct Date: June 18, 2001

Vector Constructs/Line Numbers Planted: [CBI deleted]

Purpose of Trial: [Demonstration tria] - CBI

Field Monitoring for Disease Susceptibility: [CBI deleted]

Field Monitoring for Insect Susceptibility: [CBI deleted]

Field Monitoring for Plant Growth, Weediness and Plant Stand Characteristics: [CBI deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI deleted]

Additional Comments: [CBI deleted]